ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: March 22, 2013
PROJECT ANALYST: Bernetta Thorne-Williams
ASSISTANT CHIEF Martha J. Frisone

PROJECT I.D. NUMBER: Q-10068-12/ Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center/ Add 65 acute care beds and construct a new cancer center tower/ Pitt County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

CA

The 2012 State Medical Facilities Plan (SMFP) identifies a need determination for 65 new acute care beds in the Pitt/Greene/Hyde service area. The only applicant, Pitt County Memorial Hospital, Incorporated (PCMH) d/b/a Vidant Medical Center (VMC), proposes to add 65 acute care beds and construct a new cancer center tower. VMC is currently licensed for 748 acute care beds which are located in Pitt County. Following completion of Project I.D. # Q-8769-11 (add 48 acute care beds), VMC will be licensed for 782 acute care beds (14 of the 48 beds are already licensed). The applicant proposes to add no more than 65 acute care beds for a total of 874 acute care beds. Thus, the application is conforming to the need determination in the 2012 SMFP.

Additionally, the following three policies are applicable to this review; Policy AC-5: Replacement of Acute Care Bed Capacity, Policy GEN-3: Basic Principles and Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.

Policy AC-5: Replacement of Acute Care Bed Capacity states:

"Proposals for either partial or total replacement of acute care beds (i.e., construction of new space for existing acute care beds) shall be evaluated against the utilization of the total number of acute care beds in the applicant's hospital in relation to utilization targets found below. For hospitals ***not*** *designated by the Center for Medicare and Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed 'days of care' shall be counted. For hospitals designated by the Center for Medicare and Medicaid Services as Critical Access Hospitals, in determining utilization of acute care beds, only acute care bed 'days of care'* ***and*** *swing bed days (i.e., nursing facility days of care) shall be counted in determining utilization of acute care beds. Any hospital proposing replacement of acute care beds must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application. Additionally, if the hospital is a Critical Access Hospital and swing bed days are proposed to be counted in determining utilization of acute care beds, the hospital shall also propose to remain a Critical Access Hospital and must demonstrate the need for maintaining the swing bed capacity proposed within the application. If the Critical Access Hospital does not propose to remain a Critical Access Hospital, only acute care bed "days of care" shall be counted in determining utilization of acute care beds and the hospital must clearly demonstrate the need for maintaining the acute care bed capacity proposed within the application.*

Facility Average Daily Census	*Target Occupancy of Licensed Acute Care Beds*
1 – 99	*66.7%*
100 – 200	*71.4%*
Greater than 200	*75.2%*

Policy AC-5 is applicable to this review because the VMC proposes to construct a new Cancer Center Tower and relocate 31 of its existing 52 general medical/surgical acute care beds in its current oncology department to the proposed cancer center tower.

The following table illustrates historical and projected acute care bed utilization as reported in Section IV, pages 64-68.

Fiscal Year	# of Licensed Acute Care Beds	# of Patient Days	Average Daily Census	Percent Change	Average Occupancy Rate
2012 Actual	748	225,047	617	NA	82.4%
2013 Projected	782	233,252	639	3.6%	81.7%
2014 Projected	782	241,247	661	3.4%	84.5%
2015 Projected	782	248,885	682	3.2%	87.2%
2016 Projected	782	256,112	702	2.9%	89.7%
2017 Projected	782	263,110	721	2.7%	92.2%
2018 Projected - Year 1	847	269,487	738	2.4%	87.2%
2019 Projected - Year 2	847	275,469	755	2.2%	89.1%
2020 Projected - Year 3	847	281,015	770	2.0%	90.9%

*** Source: Section IV.1, page 66. ADC and % change rounded to closest whole number.**

As shown in the table above, VMC projects that the occupancy rate for 847 licensed acute care beds will be 90.9% in Project Year 3, which exceeds the target occupancy rate of 75.2 percent. The occupancy rate for the 748 licensed acute care beds in FY2012 was 82.4%

Projected utilization is based on reasonable, credible, and supported assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates the need to maintain the acute care bed capacity proposed in this application and the application is consistent with Policy AC-5.

Policy GEN-3: Basic Principles states:

> *"A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area."*

<u>Maximize Healthcare Value</u>

In Section III.2, page 56, the applicant states:

"The proposed project is consistent with the basic principles. Throughout this application, detailed information is provided on the proposed project to support current and future approaches to:

- *promote safety and quality,*
- *promote equitable access, particularly for medically underserved, and*
- *maximize healthcare value for the resources expanded."*

In Section III.2, page 57, the applicant states:

"The proposed project is being developed to meet hospital 'mission' objectives that focus, in part, on meeting the care needs and the education/research needs of the residents in eastern NC. At its core, the proposed project is based on VMC's need for additional general acute care inpatient beds. However, in addition to gaining needed inpatient capacity, the proposed project also addresses a major health issue in ENC (Eastern North Carolina) *– cancer. Vidant Health as a system is embarking on a new era in cancer care. Inspired by the commitment to provide quality care close to home for eastern North Carolina residents, Vidant Health is working to develop and broaden the system's cancer program. To accomplish this, Vidant Health is refining each element in the continuum of care, from screening and early detection to the provision of state of the art medical, surgical and radiological cancer treatment. Developing a robust cancer program is one of Vidant Health's top priorities over the next five years. … Vidant Health intends to dedicate significant resources to this endeavor, and expects to build a program that will earn a reputation as a regional referral cancer center. …* [T]*he system views the proposed project as the key cornerstone in tipping the scale in ENC towards survivorship and away from late stage diagnosis and higher mortality rates. Therefore, the proposed project costs, balance against the benefits to patients, community, physicians and staff, yield significant value …"*

<u>Promote Safety and Quality</u>

In Section II.2, page 56, the applicant states:

"VMC has a comprehensive patient safety and quality improvement plan that monitors, evaluates and improves health care processes and outcomes, supports Medical Staff review, and is consistent with TJC standards. The hospital's Quality Improvement (QI) Program ensures that all patient care and support services:

- *focus on patient safety through process improvement and education,*
- *provide effective and efficient quality serves, and*
- *meet patient expectations through targeted customer service initiatives.*

This QI Plan covers all services at VMC. …

The proposed project will be developed to adhere to the comprehensive QI Plans already in place. This will assure the proposed project will promote safety and quality."

See Appendix G for a copy of the Applicant's Patient Safety, Quality Improvement and Patient Experience Plan.

Promote Equitable Access

In Section III.2, page 57, the applicant states:

"VMC is an essential access point for the medically underserved population in eastern NC. As a mission driven, not-for-profit organization, VMC has a long history of meeting the needs of the medically underserved. As evidenced in the hospital's payer mix and policies. VMC accepts all patients seeking essential care regardless of ability to pay. VMC would operate the proposed project under the same policies that have governed VMC's historical service to the community.

Furthermore, the proposed addition of 65 acute care beds would address the hospital's ability to ensure access to care for patients in the region. The proposed project would help eliminate access barriers and address the hospital's current and future demand, including the needs of the medically underserved."

The applicant adequately demonstrates that the proposed project will maximize healthcare value, promote safety and quality and promote equitable access to medically underserved groups. See Criterion (13) for additional discussion relating to promoting equitable access which is incorporated hereby as if set forth fully herein. Therefore, the application is consistent with this policy.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building

Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section III.2, pages 58-59, the applicant states:

"VH and VMC are committed to constructing facilities that are energy efficient and promote water conservation. Specifically related to the proposed project, … VH and VMC will, as part of the design phase, submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation.

…

VH and VMC will conform to the energy efficiency and water conservation rules, codes and standards implemented by The Construction Section of the Division of Health Service Regulation and required by the North Carolina State Building Code. During the design of this project the VH Office of Facilities and Properties, in conjunction with the VMC Plant Operators Depart, will work with the project Architects and Engineers to assure that the latest technologies for enhanced building energy and water conservation are evaluated for the project and incorporated into the facility were most appropriate. The goal of this effort will be to maximize energy efficiency and water conservation while creating the best possible care and healing environments for our patients.

[A] *plan for energy efficiency and water conservation will be developed during the design phase of the project. …*
…"

The applicant adequately demonstrates the proposal includes a plan to assure improved energy efficiency and water conservation.

In summary, the applicant adequately demonstrated the proposed application is consistent with the need determination in the 2012 SMFP. Additionally, the application is consistent with Policies AC-5, GEN-3 and GEN-4 and is conforming to this criterion subject to the condition found at the end of Criterion (4).

(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, Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center, is the only existing acute care hospital in the Pitt/Greene/Hyde service area. VMC currently operates 861 acute care beds in Pitt County. Following completion of Project I.D. # Q-8769-11 (add 48 acute care beds), VMC will be licensed for 909 acute care beds. In this application, VMC proposes to add 65 acute care beds and construct a 369,110 square foot, six-story cancer center tower that will be physically connected to the existing facility. The proposal consists of the following components:

1st Floor – Outpatient Cancer Services:

In Section II.1(a), page 10, the applicant states:

"The first floor will allow VMC to relocate its existing outpatient oncology services into a state-of the art facility to better diagnose and treat cancer patients in the region. Services planned for relocation include the existing CyberKnife, Gamma knife, chemotherapy, and PET. The space will also allow for a dedicated oncology pharmacy, lobby, oncology resource library, administrative suite, radiation support, and general support/storage areas. The first floor will also allow space for VMC to lease outpatient clinic space to local Vidant Medical Group (VMG), ECU and/or private practice oncologists."

2nd and 4th Floors – Inpatient Cancer Services:

In Section II.1(a), page 10, the applicant states:

"Designed to mirror the universal bed concept … the second and fourth floors will house 48 inpatient beds on each floor for a total of 96 beds. The space will also allow for all necessary ancillary and support space."

3rd Floor – Mechanical:

In Section II.1(a), page 10, the applicant states:

"[T]*he third floor of the proposed tower will contain all the necessary mechanical components required for the operation of the tower."*

5th and 6th Floors – Offices and Support:

"The fifth and sixth floors will be designed for future expansion of inpatients [sic] *beds, consistent with longer range master facility planning. Until that time, these floors will provide space for offices, conference rooms, on-call suites, resident work space, storage, etc."*

Population to be Served

In Section III.1(a), page 40, the applicant states:

"As the only acute care hospital in the Pitt/Greene/Hyde acute care service area, VMC is the primary provider of hospital services in this area. As such, a significant number of residents in these counties come to VMC for care."

The following tables illustrate historical and projected patient origin for services at VMC including data for the proposed service components included in new cancer center tower, as reported by the applicant in Section III.4(b), page 60, and Appendix S.

Historical Patient Origin

FY 2012					
County	**All Admissions (IP and OP)**	**% of Total**	**County**	**All Admissions (IP and OP)**	**% of Total**
Pitt	176,395	54.5%	Duplin	2,978	0.9%
Beaufort	19,299	6.0%	Northampton	2,163	0.7%
Lenoir	13,529	4.2%	Chowan	1,668	0.5%
Edgecombe	11,253	3.5%	Pamlico	967	0.3%
Martin	11,247	3.5%	Hyde	936	0.3%
Wilson	9,836	3.0%	Jones	831	0.3%
Wayne	9,693	3.0%	Dare	699	0.2%
Greene	9,411	2.9%	Perquimans	696	0.2%
Craven	9,135	2.8%	Pasquotank	629	0.2%
Nash	6,950	2.1%	Tyrrell	618	0.2%
Onslow	5,944	1.8%	Gates	322	0.1%
Halifax	4,973	1.5%	Currituck	136	0.0%
Bertie	4,252	1.3%	Camden	106	0.0%
Hertford	3,286	1.0%	All Other*	9,608	3.0%
Carteret	3,231	1.0%	Grand Total	323,925	100.0%
Washington	3,134	1.0%	* Areas outside of ENC		

	FY 2012		FY 2018		FY 2019	
County	**# of Inpatient Admissions**	**% of Total**	**# of Inpatient Admissions**	**% of Total****	**# of Inpatient Admissions**	**% of Total****
Pitt	93,218	35.2%	109,924	35.2%	112,216	35.2%
Beaufort	14,523	5.5%	17,126	5.5%	17,483	5.5%
Lenoir	13,751	5.2%	16,215	5.2%	16,553	5.2%
Edgecombe	13,079	4.9%	15,423	4.9%	15,745	4.9%
Wilson	11,450	4.3%	13,502	4.3%	13,784	4.3%
Craven	10,907	4.1%	12,862	4.1%	13,130	4.1%
Wayne	10,881	4.4%	12,831	4.4%	13,099	4.4%
Nash	10,026	3.8%	11,823	3.8%	12,069	3.8%
Onslow	9,711	3.7%	11,451	3.7%	11,690	3.7%
Martin	9,670	3.6%	11,403	3.6%	11,641	3.6%
Halifax	8,459	3.2%	9,975	3.2%	10,183	3.2%
Greene	7,499	2.8%	8,843	2.8%	9,027	2.8%
Bertie	6,604	2.5%	7,788	2.5%	7,950	2.5%
Duplin	4,891	1.8%	5,768	1.8%	5,888	1.8%
Hertford	4,777	1.8%	5,633	1.8%	5,751	1.8%
Carteret	4,427	1.4%	5,220	1.4%	5,239	1.4%
Washington	4,042	1.5%	4,766	1.5%	4,866	1.5%
Northampton	3,764	1.4%	4,439	1.4%	4,531	1.4%
Chowan	2,981	1.1%	3,515	1.1%	3,589	1.1%
Jones	1,245	0.5%	1,468	0.5%	1,499	0.5%
Perquimans	1,188	0.4%	1,401	0.4%	1,430	0.4%
Hyde	1,113	0.4%	1,312	0.4%	1,340	0.4%
Dare	1,088	0.4%	1,283	0.4%	1,310	0.4%
Pasquotank	932	0.4%	1,099	0.4%	1,122	0.4%
Pamlico	850	0.3%	1,002	0.3%	1,023	0.3%
Tyrrell	687	0.3%	810	0.3%	827	0.3%
Gates	599	0.2%	706	0.2%	721	0.2%
Currituck	252	0.1%	297	0.1%	303	0.1%
Camden	207	0.1%	244	0.1%	249	0.1%
All Other*	12,341	4.7%	14,553	4.7%	14,856	4.7%
Grand Total	265,162	100.0%	312,683	100.0%	319,202	100.0%

*All Other represents all other counties and states outside ENC.
** Projected percentage of totals calculated by the project analyst.

Chemotherapy

	FY 2012		FY 2018		FY 2019	
County	**# of IP & OP Visits**	**% of Total**	**# of IP & OP Visits**	**% of Total****	**# of IP & OP Visits**	**% of Total****
Pitt	2,033	30.5%	2,944	30.5%	3,085	30.5%
Martin	502	7.5%	727	7.5%	762	7.5%
Beaufort	422	6.3%	611	6.3%	640	6.3%
Craven	415	6.2%	601	6.2%	630	6.2%
Lenoir	380	5.7%	550	5.7%	577	5.7%
Wilson	277	4.1%	401	4.1%	420	4.1%
Wayne	273	4.1%	395	4.1%	414	4.1%
Washington	265	4.0%	384	4.0%	402	4.0%
Edgecombe	259	3.9%	375	3.9%	393	3.9%
Nash	246	3.7%	356	3.7%	373	3.7%
Hertford	230	3.4%	333	3.4%	349	3.4%
Bertie	194	2.9%	281	2.9%	294	2.9%
Onslow	175	2.6%	253	2.6%	266	2.6%
Carteret	168	2.5%	243	2.5%	255	2.5%
Greene	157	2.4%	227	2.4%	238	2.4%
Halifax	143	2.1%	207	2.1%	217	2.1%
Duplin	114	1.7%	165	1.7%	173	1.7%
Northampton	113	1.7%	164	1.7%	171	1.7%
Chowan	42	0.6%	61	0.6%	64	0.6%
Jones	38	0.6%	55	0.6%	58	0.6%
Pamlico	38	0.6%	55	0.6%	58	0.6%
Perquimans	22	0.3%	32	0.3%	33	0.3%
Tyrrell	19	0.3%	28	0.3%	29	0.3%
Hyde	16	0.2%	23	0.2%	24	0.2%
Dare	10	0.1%	14	0.1%	15	0.1%
Pasquotank	5	0.1%	7	0.1%	8	0.1%
Currituck	4	0.1%	6	0.1%	6	0.1%
Camden	2	0.0%	3	0.0%	3	0.0%
Gates	2	0.0%	3	0.0%	3	0.0%
All Other*	112	1.7%	162	1.7%	170	1.7%
Grand Total	265,162	100.0%	312,683	100.0%	319,202	100.0%

*All Other represents all other counties and states outside ENC.

** Projected percentage of totals calculated by the project analyst.

According to information received from the applicant, 90% of the utilization of chemotherapy infusion chairs is done on an outpatient.

	CyberKnife

	FY 2012		FY 2018		FY 2019	
County	**# of IP & OP Visits**	**% of Total**	**# of s IP & OP Visits**	**% of Total****	**# of IP & OP Visits**	**% of Total****
Pitt	57	21.0%	181	21.0%	218	21.0%
Wayne	28	10.3%	89	10.3%	107	10.3%
Beaufort	22	8.1%	70	8.1%	84	8.1%
Wilson	17	6.3%	54	6.3%	65	6.3%
Carteret	16	5.9%	51	5.9%	61	5.9%
Nash	16	5.9%	51	5.9%	61	5.9%
Onslow	16	5.9%	51	5.9%	61	5.9%
Craven	15	5.5%	48	5.5%	57	5.5%
Lenoir	14	5.1%	45	5.1%	53	5.1%
Edgecombe	13	4.8%	41	4.8%	50	4.8%
Bertie	12	4.4%	38	4.4%	46	4.4%
Halifax	9	3.3%	29	3.3%	34	3.3%
Hertford	9	3.3%	29	3.3%	34	3.3%
Martin	9	3.3%	29	3.3%	34	3.3%
Tyrrell	5	1.8%	16	1.8%	19	1.8%
Jones	4	1.5%	13	1.5%	15	1.5%
Chowan	1	0.4%	3	0.4%	4	0.4%
Dare	1	0.4%	3	0.4%	4	0.4%
Duplin	1	0.4%	3	0.4%	4	0.4%
Greene	1	0.4%	3	0.4%	4	0.4%
Hyde	1	0.4%	3	0.4%	4	0.4%
Pamlico	1	0.4%	3	0.4%	4	0.4%
Washington	1	0.4%	3	0.4%	4	0.4%
All Other*	3	1.1%	10	1.1%	11	1.1%
Grand Total	272	100.0%	866	100.0%	1,039	100.0%

*All Other represents all other counties and states outside ENC.
** Projected percentage of totals calculated by the project analyst.
According to information received from the applicant, 90% of all Cyberknife procedures are performed on outpatient basis.

	Gamma Knife

	FY 2012		FY 2018		FY 2019	
County	**# of IP & OP Visits**	**% of Total**	**# of IP& OP Visits**	**% of Total****	**# of IP & OP Visits**	**% of Total****
Pitt	18	22.8%	33	22.8%	34	22.8%
Craven	10	12.7%	18	12.7%	19	12.7%
Beaufort	8	10.1%	15	10.1%	15	10.1%
Lenoir	8	10.1%	15	10.1%	15	10.1%
Carteret	6	7.6%	11	7.6%	61	7.6%
Martin	5	6.3%	9	6.3%	10	6.3%
Onslow	5	6.3%	9	6.3%	10	6.3%
Halifax	3	3.8%	6	3.8%	6	3.8%
Wayne	3	3.8%	6	3.8%	6	3.8%
Edgecombe	2	2.5%	4	2.5%	4	2.5%
Nash	2	2.5%	4	2.5%	4	2.5%
Pasquotank	2	2.5%	4	2.5%	4	2.5%
Bertie	1	1.3%	2	1.3%	2	1.3%
Chowan	1	1.3%	2	1.3%	2	1.3%
Dare	1	1.3%	2	1.3%	2	1.3%
Duplin	1	1.5%	2	1.5%	2	1.5%
Greene	1	1.3%	2	1.3%	2	1.3%
Hertford	1	1.3%	2	1.3%	2	1.3%
Washington	1	1.3%	2	1.3%	2	1.3%
Grand Total	79	100.0%	145	100.0%	151	100.0%

** Projected percentage of totals calculated by the project analyst.
According to information received from the applicant 90%, of all Gamma Knife procedures are performed on outpatient basis.

	PET Scanner		
	FY 2012	**FY 2018**	**FY 2019**

County	# of IP & OP Visits	% of Total	# of IP & OP Visits	% of Total**	# of IP & OP Visits	% of Total**
Pitt	482	28.7%	825	28.7%	887	28.7%
Beaufort	232	13.8%	397	13.8%	427	13.8%
Martin	97	5.8%	166	5.8%	179	5.8%
Edgecombe	91	5.4%	156	5.4%	168	5.4%
Lenoir	78	4.6%	134	4.6%	144	4.6%
Nash	66	3.9%	113	3.9%	121	3.9%
Bertie	62	3.7%	106	3.7%	114	3.7%
Hertford	57	3.4%	98	3.4%	105	3.4%
Onslow	57	3.4%	98	3.4%	105	3.4%
Craven	48	2.9%	82	2.9%	88	2.9%
Wilson	47	2.8%	80	2.8%	87	2.8%
Chowan	45	2.7%	77	2.7%	83	2.7%
Washington	43	2.6%	74	2.6%	79	2.6%
Carteret	42	2.5%	72	2.5%	77	2.5%
Halifax	41	2.4%	70	2.4%	75	2.4%
Wayne	37	2.2%	63	2.2%	68	2.2%
Greene	34	2.0%	58	2.0%	63	2.0%
Duplin	30	1.8%	51	1.8%	55	1.8%
Northampton	24	1.4%	41	1.4%	44	1.4%
Hyde	13	0.8%	22	0.8%	24	0.8%
Pamlico	9	0.5%	15	0.5%	17	0.5%
Perquimans	6	0.4%	10	0.4%	11	0.4%
Dare	5	0.3%	9	0.3%	9	0.3%
Tyrrell	5	0.3%	9	0.3%	9	0.3%
Gates	3	0.2%	5	0.2%	6	0.2%
Jones	3	0.2%	5	0.2%	6	0.2%
Pasquotank	3	0.2%	5	0.2%	6	0.2%
All Other*	22	1.3%	10	1.3%	11	1.3%
Grand Total	1,682	100.0%	2,880	100.0%	3,096	100.0%

*All Other represents all other counties and states outside NC.
** Projected percentage of totals calculated by the project analyst.
According to information received from the applicant, 90% of all PET scanner procedures are performed on outpatient basis.

	Observation - Outpatient Services					
	FY 2012		FY 2018		FY 2019	
County	# of	% of	# of	% of	# of	% of

	OP Visits	Total	OP Visits	Total**	OP Visits	Total**
Pitt	12,317	43.9%	16,131	43.9%	16,293	43.9%
Beaufort	1,803	6.4%	2,361	6.4%	2,385	6.4%
Lenoir	1,529	5.5%	2,003	5.5%	2,023	5.5%
Wayne	1,256	4.5%	1,645	4.5%	1,661	4.5%
Martin	1,140	4.1%	1,493	4.1%	1,508	4.1%
Edgecombe	1,100	3.9%	1,441	3.9%	1,445	3.9%
Wilson	1,035	3.7%	1,356	3.7%	1,369	3.7%
Greene	982	3.5%	1,286	3.5%	1,299	3.5%
Craven	872	3.1%	1,142	3.1%	1,153	3.1%
Nash	735	2.6%	963	2.6%	972	2.6%
Onslow	676	2.4%	885	2.4%	894	2.4%
Bertie	547	2.0%	716	2.0%	724	2.0%
Halifax	545	1.9%	714	1.9%	721	1.9%
Hertford	446	1.6%	584	1.6%	590	1.6%
Duplin	418	1.5%	547	1.5%	553	1.5%
Carteret	381	1.4%	499	1.4%	504	1.4%
Washington	317	1.1%	415	1.1%	419	1.1%
Northampton	276	1.0%	361	1.0%	365	1.0%
Chowan	181	0.6%	237	0.6%	239	0.6%
Hyde	107	0.4%	140	0.4%	142	0.4%
Jones	100	0.4%	131	0.4%	132	0.4%
Tyrrell	88	0.3%	115	0.3%	116	0.3%
Pamlico	86	0.3%	113	0.3%	114	0.3%
Perquimans	80	0.3%	105	0.3%	106	0.3%
Dare	78	0.3%	102	0.3%	103	0.3%
Pasquotank	78	0.3%	102	0.3%	103	0.3%
Gates	29	0.1%	38	0.1%	38	0.1%
Camden	10	0.0%	13	0.0%	13	0.0%
Currituck	8	0.0%	10	0.0%	11	0.0%
All Other*	819	2.9%	1,073	2.9%	1,083	2.9%
Grand Total	28,039	100.0%	36,722	100.0%	37,090	100.0%

*All Other represents all other counties and states outside ENC.
. ** Projected percentage of totals calculated by the project analyst.

In Appendix S, the applicant states, *"VMC assumes future distribution to approximate historical experience."*

In Section VI.1, page 82, the applicant describes how the residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and

other underserved groups. The applicant provides the following table which illustrates access provided by the applicant to medically underserved groups.

	Medically Underserved	***Seniors***	***Women***	***Minority***
Inpatients	*32.2%*	*34.7%*	*51.6%*	*49.7%*
Chemotherapy	*23.2%*	*39.0%*	*51.2%*	*50.9%*
CyberKnife	*14.7%*	*55.5%*	*57.3%*	*33.8%*
Gamma Knife	*13.9%*	*33.0%*	*47.0%*	*25.0%*
PET	*29.9%*	*49.0%*	*52.9%*	*33.0%*
Observation	*26.1%*	*36.2%*	*50.7%*	*48.3%*

The applicant adequately identified the population it proposes to serve.

Need for the Proposed Project

The applicant states the need to add additional acute care beds and expand, relocate and consolidate the oncology services at VMC is based on the following factors:

- Need determination identified in the 2012 SMFP
- Historical and projected growth (all services)
- Consolidation of oncology services
- Average daily census (oncology services)

Need Determination Identified in the 2012 SMFP

In Section III.1, page 38, the applicant states:

> *"The 2012 State Medical Facilities Plan (SMFP) identifies a need for 65 additional acute care inpatient beds in the Pitt/Greene/Hyde service area. As the only existing acute care hospital in this service area, Vidant Medical Center (VMC) believes the best option to address the identified need is to place the beds in a new bed tower physically connected to the existing facility …"*

Historical and Projected Growth (All Services)

In Section III.1, pages 38-42, the applicant states:

> *"The need for additional beds is driven exclusively by the significant growth in inpatient days at VMC. Over the last several years, VMC has experienced substantial growth in the demand for this service. In fact, over the last six years alone, VMC has experienced an 18% (3.4% per year) increase in the number of inpatient days (excluding psych, rehab and normal newborn).*

… In fact, in FY2012, VMC still operated at 84.0% occupancy. This is above the SMFP recommended occupancy rate of 78% for hospitals of its size (>400 ADC). … Within the next five years, VMC will operate at 92.2% occupancy by 2017… .

VMC cannot efficiently or effectively meet the demand for inpatient acute care services operating at an occupancy rate greater than 78% and especially not at over 92% occupancy. The 65 new beds VMC is proposing to add provides some additional capacity, … this is a short term solution, since occupancy is still projected to be above 78% by 2018 when the proposed new beds are operational (87.2 occupancy). With the proposed new beds, VMC will operate at 90.9% occupancy in FY2020 …

Operating above 78% occupancy significantly hinders access. VMC serves a unique role in eastern North Carolina (ENC). Specifically, the hospital serves as the:

- *General Acute Community Hospital for the Pitt/Green/Hyde Acute Care Service Area*

  As the only acute care hospital in the Pitt/Greene/Hyde acute care service area, VMC is the primary provider of hospital services to this area. As such, a significant number of residents in these counties to VMC for care. … [A]*lmost 166,000 patients from these counties came to VMC for outpatient care (60% of total OPS) and over 21,000 for inpatient care (46% of total IPs).*

- *Destination For Complex and Tertiary Patients Residing Outside of the Pitt/Greene Acute Care Service Area*

  As the only tertiary academic medical center in ENC, patients living in other areas of the region outside the Pitt/Green/Hyde service area rely heavily on VMC for care, particularly complex and tertiary care. [A]*lmost 112,000 patients from counties beside Pitt/Greene/Hyde came to VMC for outpatient care (40% of total Ops) and over 25,000 for inpatient care (54% of total IPs).*

- *Major Referral Center For Community Hospitals Located in ENC*

  As the only tertiary academic referral center in ENC, the community hospitals and other health care facilities in the region rely heavily on VMC to accept patient transfers when the patients' medical needs exceed the capabilities of these smaller facilities. In fact, … VMC received over 9,400 patient transfers from other healthcare facilities in FY12 (1 out of every 5 admissions). This represents almost 26 transfers per day on average or 1.1 per hour. …

VMC also serves as a major teaching and learning site for many health care professional training programs in the region, is the leading center in the region for research and clinical trails, provides the highest concentration of specialty physicians in the region, and provides access to state-of the-art technology … .

However, as a direct result of operating above 78% occupancy, VMC is experiencing capacity constraints that hinder access to inpatient services. One area that is impacted the greatest is patient transfers from regional facilities. In FY2011, VMC was not able to accept over 850 patient transfers from ENC hospitals because of capacity constraints (almost 9% of requests). This means on average, almost 2 1/2 patients per day cannot be admitted to VMC for care because there were no appropriate beds available. These patients were forced to be transferred to another hospital outside of ENC for care. For many people in ENC, especially in the more poor and rural portions of the service area, transferring outside of ENC can become a significant financial and emotional hardship. In addition, many patients that come directly to VMC are routinely held for significant periods of time in the ED until a bed becomes available.

… With over 30% of inpatient admissions coming from medically underserved individuals, the need to ensure adequate access become even greater. With the current number of acute care inpatient beds, VMC cannot guarantee that resources will be available when needed. Therefore, in order to address the capacity issue the hospital is currently facing and is anticipated to continue facing in the future, VMC is proposing to add 65 additional acute care inpatient beds. …"

In Section II, page 11, the applicant states the type of bed/services to be added or relocated as a result of the proposed addition of 65 acute care beds are as follows:

"VMC is proposing to add 8 new med/surg ICU beds, 57 new general med/surg beds as well as relocate 31 existing oncology general med/surg beds to the new tower. … Specifically, VMC will:

- *Add 8 new med/surg ICU beds to the new cancer tower …*
- *Add 57 new med/surg oncology beds (16 intermediate and 41 general) to the new cancer tower …*
- *Relocate 31 of the existing 52 general med/surg oncology beds that are currently in the existing facility to the new cancer tower …*
- *Convert 10 of the vacated beds* [sic] *spaces on 1 East created from relocating 31 existing general med/surg oncology beds to outpatient observation beds. NOTE: Prior to the completion of VMC's 48 bed CON (Q-8769-11). 1 East was a dedicated 10 bed outpatient observation unit. The proposed project*

allows VMC to convert this area back to its original function with no capital cost required.

- *Convert the remaining 21 vacated beds* [sic] *spaces on 3 West created from relocating 31 existing general med/surg oncology beds to non-clinical pediatric support space (offices, family space, storage, consult rooms, on-call rooms, staff support, etc.). NOTE: 2 West is VMC's dedicated unit for inpatient general pediatric beds.*

- *Convert the remaining 21 existing general med/surg oncology beds that are currently in the existing facility (52 existing – 31 relocated) to general med/surg beds … . These beds are currently located on 3 West (15 beds) and in the palliative care unit (6 beds).*

The end result is an overall net increase of:

- *8 med/surg ICU beds*
- *36 med/surg oncology beds*
- *21 general med/surg beds*
- *10 outpatient observation beds"*

Consolidation of Oncology Services

In Section II.1, page 12, the applicant states:

"[T]*he proposed project will allow VMC to relocate and consolidate its existing outpatient oncology services into a state-of-the-art facility to more efficiently and effectively diagnose and treat cancer patients in the region. Services planned for relocation include the existing CyberKnife, Gamma Knife, chemotherapy, and PET. All of these services will be relocated to the first floor of the proposed new tower. In addition, the first floor will also allow for a dedicated oncology pharmacy, lobby, oncology resource library, administrative suite, radiation support, and general support/storage areas. The first floor will also allow space for VMC to lease outpatient clinic space to local Vidant Medical Group (VMG), ECU and/or private practice oncologists.*

The CyberKnife and Gamma Knife are currently housed in space VMC leases from ECU. After completion of the proposed project, the vacated space created by relocating these two services will revert back to ECU. VMC does not intend to continue leasing these spaces upon project completion. The existing PET scanner is located in the existing Radiology Department. The vacated spaced created by

relocating this service will be used for needed non-clinical support space for radiology services. The existing chemotherapy infusion area is located on 1 East, which is adjacent to the existing surgical suite. The vacated space created by relocating this service will be used for needed non-clinical sport space for surgical services."

In Section III.1, pages 44-48, the applicant states:

"On average in FY12, there were almost 93 cancer patients in inpatient beds at VMC. VMC currently dedicates 52 inpatient beds to cancer patients scattered throughout the hospital in three dedicated oncology units- a 6 bed unit in the palliative care unit, a 10 bed unit in a converted outpatient observation area (1East), and a 36 bed unit on 3 West. However, the number of beds assigned to these dedicated units is not sufficient to accommodate the average daily census of almost 93 oncology patients. This means only 56% of the total oncology patients at VMC are placed in the oncology units (almost 1 out of every 2). The remaining are scattered throughout the hospital in whichever bed is available. Patients on other non-oncology units do not get the benefit of dedicated and trained oncology staff and on-site support services patients on the oncology units have access to. Bringing the staff and services to other parts of the hospital in order to meet these needs currently creates operational and clinical inefficiencies. In addition, oncologists are not as efficient since they are required to round throughout the hospital to treat and consult with oncology patients. Significant operational and clinical efficiencies as well as improvements in the standard of care can be achieved by clustering all oncology patients together.

…

Aside from the clinical and operational benefits gained by clustering oncology patients in the proposed new tower, cancer is a major health issue in eastern North Carolina.

…

ENC is not immune to the national cancer health issues. In fact, mortality rates in ENC are much worse. In ENC, approximately 6,800 residents are diagnosed with cancer each year (almost 19 per day or 1 every 77 minutes). Of those, approximately 2,900 (43%) will die from cancer (almost 8 per day or 1 every 3 hours). In terms of cancer incidence, North Carolina exceeds the national average for cancer incidence. ENC is slightly higher than the NC average. However, ENC doesn't experience a disproportionate share of cancer incidence. In fact, ENC appears to have a fairly normal distribution throughout the Quantile Intervals … . The major health issue in ENC is cancer mortality. … Most of the counties in ENC (24 out of 29) Have mortality rates in the top three Quantile Intervals.

This data suggests that the current health care infrastructure in ENC is not reaching cancer patients early enough in the disease progression to affect survivorship. Most of this is caused by the socioeconomic and demographic makeup of ENC. ENC geographically is the size of Maryland. However, most of the area is rural with population per square mile indicators significantly lower than the rest of the State. Because of this, the area is rural in nature and possesses socioeconomic indicators (poverty, concentration of 65+, unemployment, education, etc.) far worse than other areas in the State. The limited population in these rural areas is not significant enough to support many medical and surgical specialists, including oncologists. … The socioeconomic barriers that exist in ENC make it financially difficult to access even basic primary care services. Therefore, many residents in ENC wait until a health care issue becomes severe before seeking treatment. For cancer, this is the difference between increased survivorship (diagnosis at stage 1 or 2) or increased mortality (diagnosis at stage 3 or 4). The incidence and mortality data presented … would indicate barriers to access are limiting the early diagnosis and treatment of cancer patients in ENC.

…

The goal of the proposed project is to provide attractive, convenient space for both inpatient and outpatient care.

…

VMC is proposing to construct a new inpatient/outpatient bed tower dedicated to cancer patients as part of a coordinated plan to better care for patients with cancer, which will ultimately improve access to care, patient experience and outcomes. …"

The applicant adequately demonstrates the need to consolidate oncology services in the proposed tower.

Average Daily Census (Oncology Services)

"VMC analyzed the number of FY12 days, unit location, and licensed bed category of cancer patients in the hospital. Based on the analysis … VMC had an average daily census (ADC) of 92.6 cancer patients, with 63.7 in general acute care beds, 15.0 in intermediate beds, 9.8 in ICU beds, and 4.4 in subacute beds (predominately rehab). … Based on this analysis, VMC estimates the tower would have had an ADC of 67.0 cancer patients with 50.1 in general acute care beds, 11.1 in intermediate beds, 5.8 in ICU beds, and 0.0 in subacute beds."

Projected Utilization of Acute Care Beds

In Section IV.1(d) pages 64-72, the applicant provides its assumptions and the methodology used to project utilization for all services associated with the proposed project. The applicant also provides historical utilization for FY10-FY12. The data in the table below shows only FY2012.

TOTAL ACUTE CARE BEDS									
	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20
Inpatient Days	225,047	233,252	241,247	248,885	256,112	263,110	269,487	275,469	281,015
% Change	4.0%	3.6%	3.4%	3.2%	2.9%	2.7%	2.4%	2.2%	2.0%
ADC	616.6	639.0	660.9	681.9	701.7	720.9	738.3	754.7	769.9
Total Beds (Licensed)	748	782	782	782	782	782	847	847	847
Existing Beds (as of 10/1/06)	634	634	634	634	634	634	634	634	634
New Beds (Approved/Developed)	100	148	148	148	148	148	148	148	148
New Beds (Proposed)	-	-	-	-	-	-	65	65	65
% Occupancy	82.4%	81.7%	84.5%	87.2%	89.7%	92.2%	87.2%	89.1%	90.9%

In Section IV, page 68, the applicant provides its assumptions for the acute care beds, as follows in the table below.

Bed Type	*FY07-12 CAGR*	*FY12-20 CAGR*	*Growth Assumptions*
Adult ICU	*4.5%*	*1.2%*	*Even through 6 year growth trends were 4.5% per year, the growth has slowed significantly in recent years. VMC assumes growth will be closer to population growth.*
Adult General Med/Surg	*4.6%*	*3.4%*	*VMC has experienced significant growth in general med/surg services, particularly in recent years. This is mostly attributable to addint 116 new acute care beds. VMC estimates the growth trend will begin to slow towards population growth.*
Pediatric ICU	*-3.7%*	*1.4%*	*VMC estimates the opening of the Children's Hospital in FY13 will have an impact to relieve pent up demand and then begin to slow towards historical rates.*
Pediatric General Med/Surg	*1.6%*	*2.8%*	*VMC estimates the opening of the Children's Hospital in FY13 will have an impact to review pent up demand and then begin to slow towards historical rates.*
Level II-IV Neonatal	*-1.3%*	*1.7%*	*Most of the recent decline in volume is caused in the decrease in the birth rate due to the current economy. VMC believes growth will return to historical rates as the economy recovers.*
Obstetrics	*-1.4%*	*1.0%*	*Most of the recent decline in volume is cased in the decrease in the birth rate due to the current economy. VMC believes growth will return to historical rates as the economy recovers.*
Psych	*-0.1%*	*1.0%*	*VMC estimates behavioral health services will approximate population growth.*
Rehab	*2.9%*	*1.5%*	*VMC estimates rehab services will be slightly above the population growth due to the relatively high concentration of senior* [sic] *in VMC's service area.*
Level I Nursery	*0.7%*	*1.0%*	*Most of the recent decline in volume is caused in the decrease in the birth rate due to the current economy. VMC believes growth will return to historical rates as the economy recovers.*
TOTAL	*3.0%*	*2.6%*	*Overall, the assumptions are considered conservative given the projected compound average growth rate is below VMC's historical experience.*

VMC projects that the utilization rate for the 847 acute care beds will be 90.9% in the third year of operations following completion of the proposed project, which exceeds the rate required by 10A NCAC 14C .3803(a). Projected utilization of acute care beds is based on reasonable, credible and supported assumptions regarding growth in utilization which is expected to continue, though at decreasing rates. The applicant adequately demonstrated the need to develop 65 new acute care beds at VMC.

Intensive Care Unit Beds

In Section II.1, page 11, the applicant states VMC proposes to add 8 new med/surg intensive care unit (ICU) beds in the new cancer center tower. VMC currently operates 104 ICU beds (excluding pediatric and neonatal ICU beds). Upon completion of the proposed project the applicant would operate 112 ICU beds (excluding pediatric and neonatal ICU beds).

In Section IV.1(d) page 65, the applicant provides its historical and projected utilization for VMC's adult ICU beds. The applicant also provides historical utilization for FY10-FY12. The data in the table below shows only FY2012.

ADULT ICU BEDS									
	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	FY20
Inpatient Days	27,915	28,250	28,589	28,932	29,279	29,631	29,986	30,346	30,710
% Change	4.3%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%	1.2%
ADC	76.5	77.4	78.3	79.3	80.2	81.2	82.2	83.1	84.1
Total Beds (Licensed)	104	104	104	104	104	104	112	112	112
Existing Beds (as of 10/1/06)	72	72	72	72	72	72	72	72	72
New Beds (Approved/Developed)	32	32	32	32	32	32	32	32	32
New Beds (Proposed)	-	-	-	-			8	8	8
% Occupancy	73.5%	74.4%	75.3%	76.2%	77.1%	78.1%	73.4%	74.2%	75.1%

On page 68, the states the compound annual growth rate (CAGR) between FY2007 and FY2012 was 4.5%. The applicant assumes a growth rate of 1.2% through project Year 3, which is approximately the population growth rate..

The applicant projects 30,710 intensive care patient days (excluding neonatal and pediatric intensive care days) by the third year (FY2020) following completion of the proposed project. With the addition of 8 new ICU beds, VMC would have a total of 112 licensed ICU beds, this would result in an average annual occupancy rate of 75.1%, which exceeds the threshold of 70% for facilities with 20 or more intensive care beds.

Projected utilization of the 112 ICU beds at VMC is based on reasonable, credible and supported assumptions regarding growth in utilization, which is expected to continue at a lower rate approximately equal to the projected population growth rate. The applicant adequately demonstrated the need to develop 8 new ICU beds at VMC.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population has for each component of the project. Therefore, the application is conforming to this criterion.

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

NA

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

C

In Section III.3, pages 59-60, the applicant describes several alternatives considered which include the following:

1) Maintain Status Quo – VMC considered maintaining the status quo, however, the applicant concluded to do nothing would not be in the best interest of the patients served at VMC.

2) Construct Additional Beds Elsewhere on VMC's Campus – VMC considering constructing space for the additional acute care beds elsewhere on campus. However, VMC rejected this idea because it was not economical to construct space on another part of the campus which would have needed its own infrastructure to support the operations of the structure.

3) Construct Additional Beds Elsewhere in Pitt, Green or Hyde Counties – VMC concluded that this alternative was not its best alternative because it would need to replicate its existing services and infrastructure to create a new facility.

4) Constructing a Cancer Center Tower to Mirror the Existing East Carolina Heart Institute (ECHI) Tower – the applicant concluded expanding its inpatient oncology beds by 36 inpatient beds, relocating and consolidating its existing oncology services into a new cancer center tower would utilize the existing services, energy plant and infrastructure. Thus, the applicant concluded that this was VMC's least costly and most effective alternative to meet the need.

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

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need to consolidate inpatient and outpatient cancer services and add 65 additional acute care beds. The application is conforming or conditionally conforming to this criterion and approved subject to the following conditions.

1. **Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall materially comply with all representations made in the certificate of need application.**

2. **Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and which would otherwise require a certificate of need.**

3. **Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall add no more than 65 acute care beds for a total of no more than 847 acute care beds upon completion of Project Q-8769-11 (add 48 acute care beds) and this project.**

4. **Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall add no more than 8 intensive care beds for a total of no more than 112 intensive care beds (excluding neonatal and pediatric intensive care beds) upon completion.**

5. **Pitt County Memorial Hospital, Incorporate d/b/a Vidant Medical Center shall submit a plan of energy efficiency and water conservation to the Construction Section, DHSR, that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation.**

6. **Prior to issuance of the certificate of need, Pitt County Memorial Hospital, Incorporated d/b/a Vidant Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein in writing to the Certificate of Need Section.**

(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

In Section VIII.1, page 100, the applicant states that the total capital cost of the project will be $183,439,682, including $2,000,000 for site costs, $114,000,000 for construction contract costs, $25,000,000 for equipment/furniture lease/purchase, $8,000,000 for architect/engineering fees, $2,325,626 for other (underwriter and other fees), $22,114,056 for financing costs, and $10,000,000 for other costs (IS / security / biomed / signage). In Section IX, page 101, the applicant states there will be no start-up or initial operating expenses associated with the proposed project. In Section VIII.3, page 96, the applicant states that the project will be funded by means of a Public Campaign ($40,000,000) and Bond Issue ($143,439,682). Appendix W contains a November 12, 2012 letter signed by the Chief Financial Officer for University Health Systems of Eastern Carolina d/b/a Vidant Health and Vidant Medical Center, which states:

> *"VH and VMC will secure $119.0 million in long-term, tax-exempt revenue bonds with an estimated capitalized interest expense and fees of $24.4 million.*
>
> *VH and VMC recognize the VMC Foundation estimates it can raise $40.0 million in external contributions specific for the proposed project …. In the event external contributions do not reach the $40.0 million target, VMC will commit up to $40.0 million in accumulated reserves to complete the proposed project.*
>
> *VH's accumulated reserves as of September 30, 2012 are $542.3 million and can support this project."*

Appendix K of the application contains the audited financial statements for Vidant Health Inc, the parent company of Vidant Medical Center, for the fiscal years ending September 30, 2011 and September 30, 2010. As of September 30, 2011, Vidant Health had $101,492,000 in cash and cash equivalents and $694,310,000 in net assets (total assets less total liabilities). The applicant adequately demonstrated the availability of sufficient funds for the capital needs of the project.

The applicant provided pro forma financial statements for the first three years of the project, for the entire hospital and the proposed Cancer Center. The applicant projects that Cancer Center revenues will exceed operating expenses in each of the first three full fiscal years, as illustrated in the table below.

Chemotherapy Patients

	Project Yr 1 10/1/17-9/30/18	Project Yr 2 10/1/18-9/30/19	Project Yr 3 10/1/19-9/30/20
Gross Patient Revenue	$94,938,507	$102,480,422	$110,093,692
Deductions from Gross Patient Revenue	$55,357,862	$59,844,062	$64,386,107
Net Patient Revenue	$39,580,645	$42,632,360	$45,707,585
Total Expenses	$31,472,081	$34,024,474	$36,621,581
Net Income	$8,108,564	$8,607,885	$9,086,004

The applicant also projects a positive net income for the entire hospital in each of the first three full fiscal years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions regarding cost and charges. See Criterion (3) for discussion of utilization projections which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrated that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

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

C

The 2012 State Medical Facilities Plan identified a need for 65 additional acute care inpatient beds in the Pitt/Greene/Hyde service area. Vidant Medical Center in Greenville is the only hospital located in the Pitt/Greene/Hyde service area. In addition, VMC is a regional, tertiary academic medical center providing care and services to residents of 28 counties in eastern North Carolina. VMC currently provides radiation and medical oncology services to the residents of eastern North Carolina. In this application, VMC proposes to add 65 inpatient acute care beds including eight additional ICU beds, and expand, consolidate and relocate its existing oncology services and related support services, to a new cancer center tower. The applicant does not propose to acquire any new equipment or to offer any new services. The applicant adequately demonstrates the need for all components of its proposal. See Criterion (3) for the discussion regarding the need for the proposal which is incorporated hereby as if fully set forth herein.

The applicant adequately demonstrates the project will not result in the unnecessary duplication of existing or approved acute care services in the Pitt/Greene/Hyde service area. Consequently, the application is conforming to this criterion.

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

C

The applicant proposes to add an additional 65 (8 intensive care medical/surgical, 21 general medical surgical, and 36 oncology care) acute care inpatient beds to VMC's existing bed complement. The applicant proposes to add staff throughout the development process of the proposed project. In Appendix E the applicant provides the current and projected staffing during the second full fiscal year for the hospital's inpatient units, as illustrated in the table below.

	CURRENT FTES	**PROJECTED FTES FY 2019**
Secretary/ Receptionist/ Clerk	163.7	197.1
RN Manager	23.2	27.9
RN Asst Manager	56.7	68.3
RN Staff	1,184.9	1,426.1
LPN	8.5	10.2
Nursing Assistant	6.9	8.3
Care Partner	335.5	403.8
Support Partner	11.3	13.6
Mental Health Technician	26.9	32.4
Other Clinical	8.8	10.5
Other Non-Clinical	0.9	1.1
Total	**1,827.2**	**2,199.6**

As illustrated in the above table, the applicant projects to add 372.4 full-time equivalent (FTE) positions by the second full fiscal year following completion of the proposed project. Furthermore, in Section VII.3(a), pages 90-91, the applicant states:

"VMC utilizes relatively constant care staff to patient ratios on all its inpatient units. Therefore, VMC expects the number of clinical staff assigned to existing, new and replaced units to increase as a direct result of an increase in census. As a result of this, VMC anticipates adding 414.3 additional clinical staff directly related to patient care on the inpatient units by FY2020 [third full fiscal year] *in order to maintain these ratios. In addition, VMC anticipates adding 76.0 additional support staff (admissions, environmental services, and guest relations) to support the proposed new bed tower…. "*

In Section VII.6(a)(b), pages 92-93, the applicant provides the recruitment and staff retention plan. In Section VII.8(a), page 94, the applicant states Dr. Brian Kuzyk will serve as the medical director. The applicant demonstrated the availability of adequate health manpower and management personnel to provide the proposed services, and therefore, the application is conforming to this criterion.

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

C

The applicant currently provides the services proposed in this application, and the necessary ancillary and support services are currently available. In Section II.2(a), page 14, the applicant states:

"As an existing regional, tertiary academic medical center, VMC currently has all ancillary and support services in place to support hospital operations …. These clinical services include (but are not limited to):

- *Pathology services*
- *Pharmacy services*
- *Rehabilitation services*
- *Inpatient care services (general, intermediate, and ICU level)*
- *Operative services (pre-op, post-op, and operating room services)*
- *Observation services*
- *Respiratory therapy services*
- *Emergency services*
- *Woundcare services*
- *Radiology services (VIR, MRI, X-ray, CT, NucMed, and ultrasound, etc.)*
- *Other diagnostic services (EKG, EP, ECHO, etc.)*
- *Anesthesiology services*
- *Cardiac catheterization services*

VMC currently provides all of these services as part of its current compliment [sic]. *Upon completion of the proposed project, these services will continue to support patients receiving services at VMC.*

Support functions such as billing, facility management, transcription, quality &, safety, patient transport, material services, dietary, housekeeping, maintenance, health information management, etc. will be provided utilizing existing services and personnel within the respective departments of the hospital as needed. …"

See Appendix I of the application for a copy of a letter from the President and Chief Nursing Officer / Senior Vice President, Patient Care Services of VMC attesting to the availability of ancillary and support services. Appendix L contains letters of support from physicians and others for the proposed project. The applicant adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

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

C

In Section II.1, pages 12-13, the applicant states:

"[T]*he proposed project will require the construction of a new 369,110 square foot, six-story bed tower that will be physically connected to the existing facility. The tower will be built adjacent to the existing ECHI bed tower and mirrors its design. The central utility plant built for the existing ECHI bed tower was constructed with the proposed new tower in mind. The plant as well as its tunnel infrastructure is sufficient to meet all the utility needs of the new proposed tower. …*

As a result of the proposed project, VMC will have several vacated areas. None of the vacated space will require major construction or renovations, only minimal refurbishment (paint, flooring, etc). Minor refurbishment costs are included in construction capital cost estimates … . The table below identifies these existing areas, their intended future use after completion of the proposed project, and the construction required."

Service	***Future Use***	***Construction***
PET	*Radiology Support*	*Refurbishment only*
Chemotherapy	*Surgery Support*	*Refurbishment only*
CyberKnife	*Revert back to ECU*	*Not Applicable*
Gamma Knife	*Revert back to ECU*	*Not Applicable*
10 Acute IP Beds (1 East)	*OP Observation*	*Refurbishment only*
21 Acute IP Beds (3 West)	*Pediatric support*	*Refurbishment only*

In Section XI.4, page 110 the applicant provides the proposed square footage for the new Cancer Center tower, as illustrated in the table below:

Cancer Center Tower		
Department/Section	**Proposed Use**	**New Construction Square Footage**
1st Floor	OP Cancer Services	113,135
2nd Floor	48 Bed IP Unit	51,195
3rd Floor	Mechanical	51,195
4th Floor	48 Bed IP Unit	51,195
5th Floor	Support Services	51,195
6th Floor	Support Services	51,195
Total		**369,110**

In Section XI.4(f), page 111, the applicant provides the cost per square feet for the proposed cancer center tower, as illustrated in the table below.

	Estimated	***Construction***	***Construction***	***Total Cost***	***Total Cost***

	Square Feet	***Cost Per Sq. Ft.***	***Cost per Bed***	***per Square Foot***	***Per Bed***
Entire Project	*369,110*	*$308.85*	*$1,753,846*	*$496.98*	*$2,822,149*

Appendix Y contains a certified cost estimate from Vidant Health's Vice President, Facilities and Properties, which states:

"This is to certify that I have reviewed the construction costs associated with the facility modifications and additions. Based on recent project experience, the budget for this project is estimated to be:

Design and Construction Costs	*$124,000,000*
Furniture/Equipment	*$ 25,000,000*
Other	*$ 10,000,000*
TOTAL PROJECT BUDGET	*159,000,000*

NOTE: The estimate above does not include any interest cost or any other fees associated with funding the proposed project."

In Section XI.6, page 112, the applicant provides the current and projected number of wards, private and semi-private rooms following the completion of Project Q-8769-11 (add 48 beds) and this project, as illustrated in the table below.

	Current		**After Completion of Project Q-8769-11**		**After Completion of the Proposed Project**	
	Room Count	Bed Count	Room Count	Bed Count	Room Count	Bed Count
Private	763	763	827	827	892	892
Semi-Private	41	82	41	82	41	82
Ward	1	16	0	0	0	0
Total	**805**	**861**	**868**	**909**	**933**	**974**

Section XI.7, pages 112-114 contains the applicant's energy efficiency and sustainability plan and water conservation plan. Appendix C contains the Site and Floor Plans. See Criterion (1) for additional discussion regarding energy conservation which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates that applicable energy saving features have been incorporated into the construction plans.

The applicant adequately demonstrates that the cost, design, and means of construction represent the most reasonable alternative for the proposal to construct a Cancer Center

Tower. Furthermore, the applicant adequately demonstrates the project will not unduly increase costs or charges. See Criterion (5) for discussion of costs and charges which is incorporated hereby as if set forth fully herein. Therefore, 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 VI.12 and VI.13, page 87, the applicant provides the payor mix during Fiscal Year 2012 for the entire hospital, oncology department, inpatient services and outpatient observation services, as illustrated in the table below:

Payor	**% of Total**						
	Entire Hospital	**Inpatient**	**Chemo**	**CyberKnife**	**Gamma Knife**	**PET**	**Outpatient Observation**
Commercial Insurance	1.3%	1.6%	0.4%	0.0%	0.0%	0.5%	1.4%
Medicaid	27.7%	27.2%	19.2%	14.7%	13.9%	27.8%	18.8%
Medicare / Medicare Managed Care	45.3%	47.0%	49.1%	68.4%	67.1%	9.6%	36.2%
Managed Care	16.7%	16.1%	24.0%	15.1%	15.6%	56.7%	31.2%
Other (Champus / Workman Comp)	4.2%	4.1%	3.3%	1.8%	3.4%	3.3%	5.1%
Self Pay / Indigent / Charity	4.8%	4.0%	4.1%	0.0%	0.0%	2.1%	7.3%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0 %**	**100.0 %**	**100.0%**

In Section VI.2, page 81, the applicant states:

> *"VMC ensures access to health care services for all patients noted* [low income persons; racial and ethnic minorities; women; handicapped persons; elderly; and other underserved persons, including the medically indigent, the uninsured and the underinsured]. *The hospital is a not-for-profit corporation formed for the purpose of providing quality hospital-related medical and health care services to all persons in its service area. Part A. 1. of VMC's Policy on Patient Rights expressly states, 'Persons seeking health care at the hospital have a right to treatments that are available and medically indicated, regardless of race, color, creed, age, sex, national origin, religion, disability status, sexual preference, or sources of payment for care.' All inpatient and outpatient services are, and would continue to be, provided in accordance with this policy."*

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Carteret County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Age 21 and older as % of Total Population	% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)
Pitt	16%	6.7%	21.3%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application. Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrated that medically underserved populations currently have adequate access to the services offered at Vidant Medical Center. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 63, the applicant states:

"VMC is bound by the Civil Rights Act, Hill-Burton Community services obligation as well as its admissions policy to provide equal access to care without discrimination and without regard to race, color, creed, national origin, or source of payment. VMC has fulfilled its required volume of uncompensated care services in compliance with Hill-Burton regulations. However, there exists into perpetuity the Hill-Burton requirement that VMC provide access to all those in need. In fact, over the last four fiscal years, VMC has provided almost $306.2 million in charity care services. Below is the four year breakout. Note: FY12 charity care figures were not available at time of filing.

FY08 = $41,776,646
FY09 = $74,044,506
FY10 = $99,545,120
FY11= $90,795,365"

See Appendix J for a copy of the applicants' Policy and Procedure regarding VMC's admission policies. In Section VI.10(a), page 86, the applicant states that there have been no civil rights access complaints filed against the hospital in the last five years. Therefore, the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section VI.14(a)(b), pages 87-88, the applicant provides the projected payor mix for the second full fiscal year (2019) of operations for the entire facility and oncology department, inpatient services and outpatient observation services, as illustrated in the table below:

	Projected Pay Mix for FY 2019						
Payor	**% of total**						
	Entire Hospital	**Inpatient**	**Chemo**	**CyberKnife**	**Gamma Knife**	**PET**	**Outpatient Observation**
Commercial Insurance	1.2%	1.6%	0.4%	0.0%	0.0%	0.5%	1.4%
Medicaid	23.0%	27.2%	19.2%	14.7%	13.9%	27.8%	18.8%
Medicare / Medicare Managed Care	44.2%	47.0%	49.1%	68.4%	67.1%	9.6%	36.2%
Managed Care	21.5%	16.1%	24.0%	15.1%	15.6%	56.7%	31.2%
Other (Champus / Workman Comp)	4.5%	4.1%	3.3%	1.8%	3.4%	3.3%	5.1%
Self Pay / Indigent / Charity	5.6%	4.0%	4.1%	0.0%	0.0%	2.1%	7.3%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0 %**	**100.0 %**	**100.0%**

As illustrated in the table above, the applicant projects a slight change in the entire hospital's payor mix, however, the applicant projects no change in the payor mix for inpatient, chemotherapy, Cyberknife, gamma knife, PET or outpatient observation services.

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

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

C

In Section VI.9(a), page 85, the applicant states:

"As in the past, patients will have access to the proposed services primarily through medical staff referrals, emergency department admissions, and patient transfers and referrals from other institutions. The services are available through normal operating hours and an emergency basis 24 hours per day, 7 days per week, 365 days a year."

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

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

C

In Section V.1(a), page 73, the applicant states:

"Education is a major component of the Vidant Medical Center … mission. The hospital is considered one of the leading training facilities for medical, nursing and allied health students in eastern NC. …

As the leading medical training facility in eastern NC, VMC maintains working agreements for medical, nursing, and allied health training with numerous educational institutions including, (but not limited to):

- *Brody School of Medicine at East Carolina University*
- *East Carolina University School of Nursing*
- *East Carolina University School of Allied Health Sciences*
- *East Carolina University School of Social Work*
- *East Carolina University Therapeutic Recreation Department*
- *Pitt Community College*
- *Lenoir Community College*
- *Beaufort County Community College*
- *Barton College of Nursing*
- *Edgecombe Community College*
- *University of North Carolina at Chapel Hill School of Nursing and Pharmacy"*

Appendix U contains a summary of VMC's clinical training agreements. The applicant demonstrates that the facility will continue to accommodate the clinical needs of health professional training programs in the area. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant operates the only tertiary academic medical center in eastern North Carolina and the only acute care hospital of any kind in the Pitt/Greene/Hyde service area.

In Section V.7, pages 79-80, the applicant discusses how the proposed addition of 65 acute care beds, including 8 new ICU beds, and the expansion, relocation and consolidation of existing oncology services will foster competition by promoting cost effectiveness, quality, and access to these services in the proposed service area. The applicant explains why it believes the addition of the 65 inpatient acute care beds and the expansion, relocation and consolidation of its existing oncology services to a newly constructed Cancer Center tower is critical to VMC's mission to provide quality care to patients residing in eastern North Carolina. See also Sections II, III, VI and VII of the application. The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area includes a positive impact on cost effectiveness, quality and access to the proposed services.

This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to develop 65 additional acute care beds, including 8 additional ICU beds, and to relocate, expand and consolidate oncology services.
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

Vidant Medical Center is accredited by the Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred within the eighteen months immediately preceding the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Acute Care Beds, promulgated in 10A NCAC 14C .3800 and Criteria and Standards for Intensive Care Services, promulgated in 10A NCAC 14C .1200. The specific criteria are discussed below.

SECTION .3800 - CRITERIA AND STANDARDS FOR ACUTE CARE BEDS

10A NCAC 14C .3802 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes to develop new acute care beds shall complete he Acute Care Facility/Medical Equipment application form.

-C- VMC used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to develop new acute care beds shall submit the following information:

(1) the number of acute care beds proposed to be licensed and operated following completion of the proposed project;

-C- In Appendix A, VMC states the hospital proposes to be licensed and operate 974 acute care beds upon completion of Project I.D. # Q-8769 and this proposed project.

(2) documentation that the proposed services shall be provided in conformance with all applicable facility, programmatic, and service specific licensure, certification, and JCAHO accreditation standards;

-C- In Section II.8, page 21, the applicant states that VMC is currently conforming with all applicable facility, programmatic, and service specific licensure, certification, and Joint Commission (TJC) accreditation standards.

(3) documentation that the proposed services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-C- In Section II.8, page 21, VMC states that the hospital currently conforms to licensure and other requirements relative to the physical environment. The applicant also states that all beds operated at VMC will be in a space that conforms to the requirements of federal, state, and regulatory bodies.

(4) if adding new acute care beds to an existing facility, documentation of the number of inpatient days of care provided in the last operating year in the existing licensed acute care beds by medical diagnostic category, as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the applicable State Medical Facilities Plan;

-C- In Section II.8, page 22, the applicant provides VMC's FY2012 inpatient days of care as classified by the Centers for Medicare and Medicaid Services according to the list set forth in the 2012 SMFP, as illustrated below:

MDC	*MDC Description*	*FY12 Days*
0	*Not Classified*	*3,716*
1	*Diseases and disorders of the nervous system*	*19,234*
2	*Diseases and disorders of the eye*	*208*
3	*Diseases and disorders of the ear, nose, mouth and throat*	*1,619*
4	*Diseases and disorders of the respiratory system*	*17,688*
5	*Diseases and disorders of the circulatory system*	*37,037*
6	*Diseases and disorders of the digestive system*	*20,651*
7	*Diseases and disorders of the hepatobiliary system and pancreas*	*6,435*
8	*Diseases and disorders of the musculoskeletal system and connective tissue*	*18,952*
9	*Diseases and disorders of the skin, subcutaneous tissue and breast*	*2,648*
10	*Endocrine, nutritional and metabolic, diseases and disorders*	*6,535*
11	*Diseases and disorders of the kidney and urinary tract*	*10,135*
12	*Diseases and disorders of the male reproductive system*	*354*
13	*Diseases and disorders of the female reproductive system*	*1,415*
14	*Pregnancy, childbirth and the puerperium*	*12,651*
15	*Newborns and other neonates with conditions originating in the perinatal period*	*26,151*
16	*Diseases and disorders of the blood, blood forming organs and immunological disorders*	*3,018*
17	*Myeloproliferative diseases and disorders, and poorly differentiated neoplasms*	*3,423*
18	*Infectious and parasitic diseases (systemic or unspecified sites)*	*13,486*
19	*Mental diseases and disorders*	*14,734*
20	*Alcohol/drug use and alcohol/drug induced organic mental disorders*	*691*
21	*Injuries, poisoning and toxic effects of drugs*	*3,877*
22	*Burns*	*19*
23	*Factors influencing health status and other contact with health services*	*19,508*
24	*Multiple significant trauma*	*2,521*
25	*Human immunodeficiency virus infections*	*1,033*
99	*Procedure/Diagnosis Related*	*17,443*
	TOTAL	*265,162*

***Note**: Inpatient days encompasses all beds including licensed acute care beds, Neonatal Level 1 (bassinet) beds, rehabilitation beds, and psychiatric beds. MDC 99 contains MS-DRGs that do not crosswalk directly back to a single MDC. These MDC these MS-DRGS fall into is dependent upon specific diagnosis and procedure information unique to each patient encounter."*

(5) the projected number of inpatient days of care to be provided in the total number of licensed acute care beds in the facility, by county of residence, for each of the first three years following completion of the proposed project, including all assumptions, data and methodologies;

-C- See Appendix H for the projected number of patient days of care for the total number of licensed acute care beds for each of the first three years following completion of the proposed project. See Section IV.1, pages 65-72, for the assumptions, data and methodologies used by the applicant to project the number of inpatient days of care.

(6) documentation that the applicant shall be able to communicate with emergency transportation agencies 24 hours per day, 7 days per week;

-C- In Section II.8, page 23, the applicant states, *"VMC is currently able to communicate with all emergency transportation agencies in eastern North Carolina 24 hours per day, seven days per week."*

(7) documentation that services in the emergency care department shall be provided 24 hours per day, 7 days per week, including a description of the scope of services to be provided during each shift and the physician and professional staffing that will be responsible for provision of those services;

-C- In Section II.8, page 24, the applicant provides documentation that as a Level 1 trauma center, VMC's emergency care department provides 24 hours per day, 7 days per week services to residents of the 28 counties within eastern North Carolina. On page 24, the applicant states, *"The ED is staffed by physicians with Board Certification in Emergency Medicine. …Specially trained staff triage and stabilize trauma patients and, along with other physicians, nurses and specialist decide within minutes how to best care for them. VMC maintains the staff, equipment and supplies needed to treat any patient that presents to the ED at any time."* See Appendix I for additional information.

(8) copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

-C- In Section II.8, page 25 the applicant states that VMC provides services to all medically necessary patients regardless of age, race, sex, creed, religion, disability or the patient's ability to pay. See Appendix J for a copy of VMC's admissions, patient rights and charity care policies and procedures.

(9) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs;

-C- In Section II.8, page 25, the applicant states that the hospital has complied with the conditions of participation with Medicare and Medicaid programs since its inception and VMC will continue to comply with those conditions of participation. The applicant further states that in

FY12 VMC had inpatient days of participation with Medicare and Medicaid that equaled almost 75%, as illustrated in the table below.

Payer	***FY12 IP Days***	***% of Total***
Medicare	*124,700*	*47.0%*
Medicaid	*72,152*	*27.2%*
Commercial	*46,917*	*17.7%*
Other	*10,908*	*4.1%*
Self Pay	*10,485*	*4.0%*
Total	***265,162***	***100.0%***

(10) documentation of the health care services provided by the applicant, and any facility in North Carolina owned or operated by the applicant's parent organization, in each of the last two operating years to Medicare patients, Medicaid patients, and patients who are not able to pay for their care;

-C- See Appendix K for a copy of Vidant Health's audited financial statements which includes a detailed description of the healthcare services provided by VH entities, in each of the last two operating years for Medicare and Medicaid patients and patients who are not able to pay for their care.

(11) documentation of strategies to be used and activities undertaken by the applicant to attract physicians and medical staff who will provide care to patients without regard to their ability to pay; and

-C- See Section II.8, page 26, where the applicant states it has a *"documented history"* of attracting physicians and medical staff who provide care to patients without regard to their ability to pay. See Appendix K for a copy of Vidant Health's audited financial statements and Section VI of the application.

(12) documentation that the proposed new acute care beds shall be operated in a hospital that provides inpatient medical services to both surgical and non-surgical patients.

-C- In Section II.8, page 26, the applicant states that VMC has provided both surgical and non-surgical services to patients since the hospital's inception. See Section II.8, page 12, for FY2012 inpatient days of care by MDC, which documents that the applicant provides surgical and non-surgical services.

(c) An applicant proposing to develop new acute care beds in a new licensed hospital or on a new campus of an existing hospital shall also submit the following information:

(1) the projected number of inpatient days of care to be provided in the licensed acute care beds in the new hospital or on the new campus, by major diagnostic category as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

(2) documentation that medical and surgical services shall be provided in the proposed acute care beds on a daily basis within at least five of the major diagnostic categories as recognized by the Centers for Medicare and Medicaid Services (CMS) according to the list set forth in the applicable State Medical Facilities Plan;

(3) copies of written policies and procedures for the provision of care within the new acute care hospital or on the new campus, including but not limited to the following:

(A) the admission and discharge of patients, including discharge planning,

(B) transfer of patients to another hospital,

(C) infection control, and

(D) safety procedures;

(4) documentation that the applicant owns or otherwise has control of the site on which the proposed acute care beds will be located; and

(5) documentation that the proposed site is suitable for development of the facility with regard to water, sewage disposal, site development and zoning requirements; and provide the required procedures for obtaining zoning changes and a special use permit if site is currently not properly zoned; and

(6) correspondence from physicians and other referral sources that documents their willingness to refer or admit patients to the proposed new hospital or new campus.

-NA- VMC does not propose to develop new acute care beds in a new licensed hospital or on a new campus of an existing hospital.

10A NCAC 14C .3803 PERFORMANCE STANDARDS

(a) An applicant proposing to develop new acute care beds shall demonstrate that the projected average daily census (ADC) of the total number of licensed acute care beds proposed to be licensed within the service area,

under common ownership with the applicant, divided by the total number of those licensed acute care beds is reasonably projected to be at least 66.7 percent when the projected ADC is less than 100 patients, 71.4 percent when the projected ADC is 100 to 200 patients, and 75.2 percent when the projected ADC is greater than 200 patients, in the third operating year following completion of the proposed project or in the year for which the need determination is identified in the State Medical Facilities Plan, whichever is later.

-C- In Section IV, page 66, the applicant projects the ADC for all acute care beds in Project Year 3 will be 769.9. The occupancy rate is projected to be 90.9%, which exceeds the 75.2% required by this Rule.

(b) An applicant proposing to develop new acute care beds shall provide all assumptions and data used to develop the projections required in this rule and demonstrate that they support the projected inpatient utilization and average daily census.

-C- See Section IV, pages 64-72, for the applicant's assumptions and data used to project inpatient utilization. The applicant adequately demonstrates that they support the projected utilization. See Criterion (3) for discussion which is incorporated hereby as if set forth fully herein.

10A NCAC 14C .3804 SUPPORT SERVICES

(a) An applicant proposing to develop new acute care beds shall document that each of the following items shall be available to the facility 24 hours per day, 7 days per week:

(1) laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) radiology services;
(3) blood bank services;
(4) pharmacy services;
(5) oxygen and air and suction capability;
(6) electronic physiological monitoring capability;
(7) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(8) endotracheal intubation capability;
(9) cardiac arrest management plan;
(10) patient weighing device for a patient confined to their bed; and
(11) isolation capability;

-C- In Section II.8, page 28, the applicant states that VMC currently provides all of the above referenced services. See Appendix I for a letter dated

November 15, 2012 from the President of Vidant Medical Center and the Chief Nursing Officer/Senior Vice President of Patient Care Services attesting to the fact that Vidant Medical Center provides and will continue to provide the above referenced services.

(b) If any item in Paragraph (a) of this Rule will not be available in the facility 24 hours per day, 7 days per week, the applicant shall document the basis for determining the item is not needed in the facility.

-NA- As an existing acute care facility, VMC currently provides all of the above referenced services 24 hours per day, seven days per week. See Appendix I for additional information.

(c) If any item in Paragraph (a) of this Rule will be contracted, the applicant shall provide correspondence from the proposed provider of its intent to contract with the applicant.

-NA- As an existing acute care facility, VMC currently provides all of the above referenced services. In Section II.8, page 28, the applicant states, *"The above named services are not, and will not, be contracted out."*

10A NCAC 14C .3805 STAFFING AND STAFF TRAINING

(a) An applicant proposing to develop new acute care beds shall demonstrate that the proposed staff for the new acute care beds shall comply with licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals.

-C- In Section II.8, page 29, the applicant states, *"VMC staff currently complies with all licensure requirements. The proposed staff for the new acute care beds shall comply with all licensure requirements set forth in Title 10A NCAC 13B, Licensing of Hospitals, and with all other regulatory requirements."* See Appendix I for additional documentation of compliance with Title 10A NCAC 13B.

(b) An applicant proposing to develop new acute care beds shall provide correspondence from the persons who expressed interest in serving as Chief Executive Officer and Chief Nursing Executive of the facility in which the new acute care beds will be located, documenting their willingness to serve in this capacity.

-C- See Section II.8, page 29, and Appendix I of the application for correspondence from the Chief Executive Officer and the Chief Nursing

Executive expressing their willingness to continue serving in their current capacity.

(c) An applicant proposing to develop new acute care beds in a new hospital or on a new campus of an existing hospital shall provide a job description and the educational and training requirements for the Chief Executive Officer, Chief Nursing Executive and each department head which is required by licensure rules to be employed in the facility in which the acute care beds will be located.

-NA- VMC is an existing acute care facility and proposes to add the 65 beds to the existing facility on the same campus.

(d) An applicant proposing to develop new acute care beds shall document the availability of admitting physicians who shall admit and care for patients in each of the major diagnostic categories to be served by the applicant.

-C- In Section II.8, page 29, the applicant states, *"VMC currently has almost 700 physicians on its medical staff with admitting privileges. These physicians admit and care for patients that cover all major diagnostic categories. …"* See Appendix L for a copy of a list of physicians by major diagnostic categories.

(e) An applicant proposing to develop new acute care beds shall provide documentation of the availability of support and clinical staff to provide care for patients in each of the major diagnostic categories to be served by the applicant.

-C- See Section II.8, page 30, and Appendix I, for documentation of the availability of support and clinical staff to provide care for patients in each of the major diagnostic categories currently served by VMC.

SECTION .1200 – CRITERIA AND STANDARDS FOR INTENSIVE CARE SERVICES

10A NCAC 14C .1202 INFORMATION REQUIRED OF APPLICANT

(a) An applicant that proposes new or expanded intensive care services shall use the Acute Care Facility/Medical Equipment application form.

-C- The applicant used the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing new or expanded intensive care services shall submit the following information:

(1) the number of intensive care beds currently operated by the applicant and the number of intensive care beds to be operated following completion of the proposed project;

-C- In Section II.8, page 30, the applicant states VMC currently has 104 intensive care beds. The applicant proposes to add eight new beds for a total of 112 intensive care beds upon project completion. See Appendix A for a listing of VMC's acute care beds by *"License Category."*

(2) documentation of the applicant's experience in treating patients at the facility during the past twelve months, including:

(A) the number of inpatient days of care provided to intensive care patients;

-C In Section II.8, page 30, and Section IV, page 65, the applicant reports that VMC provided 27,915 intensive care patient days of care in FY12.

(B) the number of patients initially treated at the facility and referred to other facilities for intensive care services; and

-C- In Section II.8, page 31, the applicant states that 3 patients were initially treated at the facility and referred to other facilities for intensive care services. The applicant notes this type of transfer is typically for burns or heart-lung transplants.

(C) the number of patients initially treated at other facilities and referred to the applicant's facility for intensive care services.

-C- In Section II.8, page 31, the applicant reports that 2,447 patients were transferred from other facilities for intensive care services (excluding pediatric and neonatal intensive care patients).

(3) the projected number of patients to be served and inpatient days of care to be provided by county of residence by specialized type of intensive care for each of the first twelve calendar quarters following completion of the proposed project, including all assumptions and methodologies;

-C- See Appendix M for the historical and projected number of patients served and inpatient days of care by county of residence and specialized type of intensive care unit. See Section IV, pages 64-72, for the

assumptions and methodologies used to project inpatient intensive days of care.

(4) data from actual referral sources or correspondence from the proposed referral sources documenting their intent to refer patients to the applicant's facility;

-C- As the only tertiary academic medical center in eastern North Carolina, and the only hospital in the Pitt/Greene/Hyde service area. VMC provides care to patients from at least 28 counties. See Appendix M for documentation of historical and projected utilization. See Appendix N for letters of support and Appendix O for a list of all the facilities that VMC has transfer agreements with.

(5) documentation which demonstrates the applicant's capability to communicate effectively with emergency transportation agencies;

-C- In Section II.8, page 31, the applicant states, *"VMC is currently able to communicate with all emergency transportation agencies in eastern North Carolina 24 hours per day, seven days per week."*

(6) documentation of written policies and procedures regarding the provision of care within the intensive care unit, which includes the following:
(A) the admission and discharge of patients;
(B) infection control;
(C) safety procedures; and
(D) scope of services.

-C- See Appendix P for documentation and written policies and procedures regarding the provision of care within the intensive care unit, including admission and discharge of patients, infection control, safety procedures, and scope of services.

(7) documentation that the proposed service shall be operated in an area organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access;

-C- See Appendix Q for a letter dated November 15, 2012 from Vidant Health's Vice President, Facilities and Properties which attests to the fact that the proposed intensive care service will be operated in an area organized as a physically and functionally distinct entity, separate from the rest of the facility, with controlled access.

(8) documentation to show that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies;

-C- See Appendix Q for documentation that the services shall be offered in a physical environment that conforms to the requirements of federal, state, and local regulatory bodies.

(9) a floor plan of the proposed area drawn to scale; and

-C- See Appendix C for a copy of the proposed floor plan drawn to scale. In Section II.8, page 33, the applicant states, *"Drawing #110 shows the proposed design for the two floors designated as inpatient units. VMC is proposing rooms labeled 33 through 40 on the second floor of the proposed new tower to be the new ICU rooms."*

(10) documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point.

-C- See Appendix C for a copy of the floor plan which documents a means of observation by unit staff of all the patients in the intensive care unit from at least one vantage point. In Section II.8, page 33, the applicant states, *"Reference … drawing #110, for documentation of a means for observation by unit staff of all patients in the unit from at least one vantage point. In addition to the main nurses' station, each four bed 'pod' has a nurse alcove. All four patients in each 'pod' can be observed from this alcove. For ICU patients, VMC staffs two nurses per 'pod' in order to provide a 2:1 patient to nurse ratio."*

10A NCAC 14C .1203PERFORMANCE STANDARDS

(a) The applicant shall demonstrate that the proposed project is capable of meeting the following standards:

(1) the overall average annual occupancy rate of all intensive care beds in the facility, excluding neonatal and pediatric intensive care beds, over the 12 months immediately preceding the submittal of the proposal, shall have been at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds; and

-C- In Section II.8, page 34, and Section IV, page 65, VMC reports that it provided 27,915 intensive care patient days of care (excluding neonatal and pediatric intensive care days) in FY 2012. With 104 ICU beds

(excluding pediatric and neonatal ICU beds) the occupancy rate was 73.5%, which exceeds the 70% required for facilities with 20 or more intensive care beds.

(2) the projected occupancy rate for all intensive care beds in the applicant's facility, exclusive of neonatal and pediatric intensive care beds, shall be at least 70 percent for facilities with 20 or more intensive care beds, 65 percent for facilities with 10-19 intensive care beds, and 60 percent for facilities with 1-9 intensive care beds, in the third operating year following the completion of the proposed project.

-C- In Section II.8, page 34, and Section IV, page 65, VMC projects it will provide 30,710 intensive care patient days (excluding neonatal and pediatric intensive care days) in FY20 (3rd year of operation). The facility would operate 112 ICU beds (excluding pediatric and neonatal ICU beds) and the occupancy rate would be 75.1%, which exceeds the 70% required for facilities with 20 or more intensive care beds.

(b) All assumptions and data supporting the methodology by which the occupancy rates are projected shall be provided.

-C- See Section IV, pages 64-72, for all assumptions and the methodology used by the applicant to support the data for projected occupancy rates.

10A NCAC 14C .1204 SUPPORT SERVICES

(a) An applicant proposing new or additional intensive care services shall document the extent to which the following items are available:

(1) twenty-four hour on-call laboratory services including microspecimen chemistry techniques and blood gas determinations;
(2) twenty-four hour on-call radiology services, including portable radiological equipment;
(3) twenty-four hour blood bank services;
(4) twenty-four hour on-call pharmacy services;
(5) twenty-four hour on-call coverage by respiratory therapy;
(6) oxygen and air and suction capability;
(7) electronic physiological monitoring capability;
(8) mechanical ventilatory assistance equipment including airways, manual breathing bag and ventilator/respirator;
(9) endotracheal intubation capability;
(10) cardiac pacemaker insertion capability;
(11) cardiac arrest management plan;

(12) patient weighing device for bed patients; and
(13) isolation capability.

-C- In Section II.8, page 35, the applicant states that VMC currently provides all of the above listed services.

(b) If any item in Subparagraphs (a)(1) - (13) of this Rule will not be available, the applicant shall document the reason why the item is not needed for the provision of the proposed services.

-NA- As an existing acute care facility, VMC currently provides all of the above referenced services.

10A NCAC 14C .1205 STAFFING AND STAFF TRAINING

The applicant shall demonstrate the ability to meet the following staffing requirements:

(1) nursing care shall be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support;

-C- See Appendix I which documents that nursing staff will be supervised by a qualified registered nurse with specialized training in the care of critically ill patients, cardiovascular monitoring, and life support.

(2) direction of the unit shall be provided by a physician with training, experience and expertise in critical care;

-C- In Section II.8, page 36, the applicant states, *"Medical direction of VMC's ICUs is currently provided by several physicians depending on the type of ICU …"* The following identifies the current medical directors by ICU type, as reported by the applicant on page 36 of the application:
"Overall Medical Director of all IP Beds – Dr. Paul Shackelford, Jr
Neurosurgery ICU – Dr. Stuart Lee and Dr. Robert James
Surgical ICU – Dr. Eric Toschlog
Medical ICU – Dr. Mark Mazer
Cardiovascular Surgery ICU 0 Dr. Joseph Elberry
Cardiac ICU – Dr. Harry DeAntonio"

See Appendix R for a copy of each physician's curricula vitae.

(3) assurance from the medical staff that twenty-four hour medical and surgical on-call coverage is available; and

-C- In Section II.8, page 36, the applicant states that VMC currently provides and will continue to provide medical and surgical on call coverage 24/7.

(4) inservice training or continuing education programs shall be provided for the intensive care staff.

-C- In Section II.8, page 36, the applicant states that VMC currently provides and will continue to provide inservice training and continuing education programs to all clinical and non-clinical staff. See Appendix I for additional documentation.