

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: August 23, 2017
Findings Date: August 23, 2017

Project Analyst: Gloria C. Hale
Team Leader: Lisa Pittman

Project ID #: R-11358-17
Facility: The Outer Banks Hospital Cancer Center
FID #: 170277
County: Dare
Applicant: The Outer Banks Hospital, Inc.
Project: Replace existing linear accelerator and relocate it to a new building across the street from the existing hospital

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

CA

The applicant, The Outer Banks Hospital, Inc. (OBH) proposes to replace an existing linear accelerator and relocate it from a leased building to a new building, The Outer Banks Hospital Cancer Center (OBHCC), across the street from the existing hospital. The OBHCC will be located at 4923 South Croatan Highway, Nags Head, and the radiation therapy service will continue to be operated as a hospital-based service. The OBHCC will be located in Dare County. Vidant Health and Chesapeake Hospital Authority are the parent companies to OBH.

Need Determination

There are no need determinations in the 2017 State Medical Facilities Plan (SMFP) applicable to this review.

Policies

There is one policy in the 2017 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, page 33.

Policy GEN-4 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 is 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.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, page 21, the applicant states that Vidant Health and OBH will work with the project’s architects, engineers and builders to assure that the latest technologies for maximizing energy efficiency and water conservation are evaluated and incorporated into the facility where appropriate. The applicant states that it will submit an Efficiency and Sustainability Plan to the Construction Section that conforms to or exceeds the energy efficiency and water conservation standards incorporated into the most recent edition of the state’s building codes.

In Section K.4(c), page 66, the applicant states that the OBHCC will be designed to be in compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption and these requirements apply to electrical power, lighting, heating, water heating, water conservation, and other systems. In addition, the applicant states that design standards for water conservation include the use of low-flow fixtures and toilets and that OBH will “*closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations.*”

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4, subject to the condition that the applicant shall develop 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, as stated in Condition (4) of Criterion (4).

Consequently, the application is conditionally conforming to this criterion.

- (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, OBH, proposes to replace an existing linear accelerator and relocate it from a leased building to a new building, OBHCC, across the street from the existing hospital. The OBHCC will be located at 4923 South Croatan Highway, Nags Head, and the radiation therapy service will continue to be operated as a hospital-based service. The OBHCC will be located in Dare County.

Patient Origin

On page 125, the 2017 SMFP states, “*A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.*” In Table 9I, page 134 of the 2017 SMFP, Dare County is included in Linear Accelerator Service Area 28, which also includes Camden, Chowan, Currituck, Gates, Pasquotank, Perquimans, and Tyrrell counties. Providers may serve residents of counties not included in their service area.

The applicant currently operates one linear accelerator at a leased facility located at 4125 South Croatan Highway, in Nags Head, Dare County, less than one mile from the proposed site. In Sections C.2 and C.3, pages 28 and 29, respectively, the applicant provides the current patient origin for Federal Fiscal Year (FFY) 2016 (October 1, 2015 – September 30, 2016) and projected patient origin (FFY2020-FFY2022) of OBHCC’s radiation therapy services, as summarized in the table below:

**OBHCC Radiation Therapy Services
Current and Projected Patient Origin**

County	Current Percent of Total Patients (FFY2016)	Projected Percent of Total Patients (FFY2020-FFY2022)
Dare	87.4%	87.4%
Currituck	9.0%	9.0%
Tyrrell	1.8%	1.8%
Beaufort	0.9%	0.9%
Camden	0.9%	0.9%
TOTAL	100.0%	100.0%

In Section C.3(c), page 29, the applicant states that the existing linear accelerator will be replaced and relocated and that the patient origin will not be significantly impacted, remaining essentially the same as historical patient origin.

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section C.1, page 22, and Section C.4, pages 30-37, the applicant discusses the need for the proposed project, summarized as follows:

- The applicant states that although the incidence of cancer in Dare County has remained stable over the last five years and mortality rates from cancer have decreased, the county has not achieved the national Healthy People 2020 benchmark of 161.4 deaths per 100,000 people. In addition, Currituck County, also within the applicant’s service area, has one of the highest cancer mortality rates in the state, ranking 9th out of 100 counties. The applicant states that cancer is not being identified early enough in Currituck County to prevent deaths, as evidenced by the low cancer incidence rate and high cancer mortality rate (pages 30-31).
- There is a higher percentage of seniors, aged 65 and over, in Dare and Currituck counties than statewide, and this population is growing at a higher rate than it is statewide. In 2015, 18.1% and 15.7% of Dare and Currituck counties’ residents, respectively, were 65 years of age and older as compared to 14.2% of the statewide population. The 65 and older population in Dare County is expected to grow by

nearly 21% by 2020 and Currituck County's is expected to grow by nearly 25% by 2020. The applicant states that cancer incidence increases in age and that nearly two-thirds of all cancer patients are expected to receive radiation therapy during the course of their treatment (page 32).

- The existing linear accelerator is 14 years old and well beyond its useful life of seven years according to a report from the American Hospital Association estimating useful life of hospital equipment. In addition, the manufacturer of the existing linear accelerator is no longer manufacturing or servicing linear accelerators, thus creating difficulty in finding spare parts and qualified individuals to provide maintenance and servicing. In addition, the existing linear accelerator is obsolete and is not capable of providing the same level of treatment options as newer technology (pages 22 and 34).
- There is a need to keep the radiation therapy service local due to the amount of time most cancer patients need to spend receiving treatments of smaller doses over a period of time. Keeping the service local will allow patients and their friends or family to lower the cost of travel, lodging, meals, lost work time, and other personal expenses that would be incurred during the course of treatment (page 33).
- The lease of the existing building housing the existing linear accelerator will end in March 2019 and the building will be sold by the owner. The replacement and relocation of the linear accelerator will enable the applicant to build a new facility across the street from the hospital which will, in turn, provide the radiation oncology patients with convenient access to all of the services that OBH provides (page 36).

The information provided by the applicant in the pages referenced above is reasonable and adequately supported.

Projected Utilization

In Section C.4, pages 36-37, and Form C in Section Q, the applicant provides tables showing the historical and projected utilization for the OBHCC linear accelerator through the first three operating years (OY) following completion of the project, FFY2020-FFY2022, which is summarized as follows:

OBHCC
Historical and Projected
Radiation Therapy Treatments
FFY2014-FFY2022

FFY	Number of Treatments	Number of Patients
2014 Actual	3,169	115
2015 Actual	3,306	116
2016 Actual	2,916	111
2017 Interim	3,006	115
2018 Interim	3,033	116
2019 Interim	3,060	117
2020 (OY1)	3,088	118
2021 (OY2)	3,116	119
2022 (OY3)	3,144	120

In Section C.4, pages 36-37, and Section Q, the applicant provides its assumptions and methodology for projecting utilization of the OBHCC linear accelerator, summarized as follows:

Step One:

The applicant provides its historical volume of radiation therapy treatments for FY14 through FY16 based on OBH's internal system.

Step Two:

The applicant uses a procedure-based forecasting tool from a vendor, Sg2, to project demand for radiation therapy treatments for FFY17 through FFY22, stating that the forecasting tool utilizes several data elements such as population growth, disease incidence, payor and regulatory changes, and others. Although the forecasting tool found that radiation therapy treatments will increase on average 1.6% per year over the next 10 years, the applicant uses a more conservative growth rate. For FFY17, the applicant states, in Section Q, that utilization is annualized based on a half year of actual utilization data from October 1, 2016 through March 31, 2017. For subsequent years of the project, interim years FFY18 through FFY19, and for the first three OYs, FFY20 through FFY22, the applicant applies the projected population growth rate for Dare County of 0.9% to project utilization.

Projected utilization of the applicant's one proposed replacement linear accelerator is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to replace and relocate one linear accelerator.

Access

In Section C.10, page 40, the applicant states:

“OBH ensures access to health care services for all patients...OBH’s EMTALA policy states, ‘It is the policy of this hospital that patients shall not be denied evaluation, screening, treatment or stabilization on the basis of means or ability to pay, race, creed, color, national origin, age, sex, or actual or perceived disability.’ All inpatient and outpatient services (including radiation therapy services at OBH) are, and would continue to be, provided in accordance with this policy.”

In Section L.1, page 71, the applicant states that 56.6% of patients receiving radiation therapy services at OBHCC were Medicare or Medicaid recipients in FFY16. In Section L.3, page 72, the applicant projects that 56.6% of patients who will receive radiation therapy services in the second operating year, FFY21, will be Medicare or Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. 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.

C

In Section D.2, pages 44-45, the applicant states that the OBHCC building to be constructed, which will house the replaced and relocated linear accelerator, will be located across the street from the OBH. The existing location of the OBHCC, and thus, the existing linear accelerator, is approximately 0.8 miles north of OBH on South Croatan Highway, the same highway that OBH is located on. The applicant states that the proposed location for the replacement linear accelerator will be in close proximity to other hospital services in order to meet the needs of the patients currently served. In addition, in Section D.4, page 45, the applicant states that there will be no negative effects regarding access for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups in need of radiation therapy services. Moreover, the applicant states, on page 45, that *“the ability to meet these needs will only be enhanced by the proposed project through facility ownership and potential reduction of inefficiencies (cost efficiency) and convenience to other OBH services (improved access).* Lastly, in Section

L.3, page 72, the applicant states that 56.6% of its patients receiving radiation therapy services in OY2 will be Medicare or Medicaid recipients.

The discussions regarding need and access found in Criteria (3) and 13(c), respectively, are incorporated herein by reference. The applicant adequately demonstrates that the proposed project will not have a negative effect 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.

In summary, the applicant adequately demonstrates that the needs of the population presently served by OBHCC will be adequately met following the proposed replacement and relocation of the linear accelerator to a newly constructed facility across the street from OBH. Therefore, the application is conforming to this criterion.

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

CA

In Section E.2, page 47, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo – The applicant states that the lease for the existing building where the OBHCC and its linear accelerator are located is expiring and will not be renewed. Therefore, maintaining the status quo is not an option and is not an effective alternative.
- Relocate Existing Equipment without Replacement – The applicant states that it considered this alternative but determined that using outdated, discontinued equipment “*is not the high standard of quality of care needed to treat effectively and cure cancer.*” Therefore, this was not the most effective alternative.

After considering the above alternatives, the applicant states that although the proposed project will be more costly, it will provide residents with “*affordable, high quality, convenient, effective, state-of-the-art radiation oncology services.*” Therefore, the proposed replacement and relocation of the linear accelerator is the most effective alternative.

Furthermore, the application is conforming or conditionally 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.

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

- 1. The Outer Banks Hospital, Inc. shall materially comply with all representations made in the certificate of need application.**
 - 2. The Outer Banks Hospital, Inc. shall acquire no more than one linear accelerator to replace one existing linear accelerator being relocated to a new site for The Outer Banks Hospital Cancer Center. The applicant shall dispose of the existing linear accelerator being replaced by removing it from North Carolina.**
 - 3. The Outer Banks Hospital, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 4. The Outer Banks Hospital, Inc. shall 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.**
 - 5. The Outer Banks Hospital, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Form F.1a, found in Section Q, the applicant states that the total capital cost is projected to be as follows:

OBHCC Linear Accelerator Projected Capital Cost

Capital Cost Category	Total
Purchase Price of Land	\$375,000
Site Preparation	\$235,000
Construction	\$2,093,650
Architect & Engineering Fees	\$252,350
Medical Equipment	\$2,800,000
Furniture	\$41,500
Other (Information Systems and Security)	\$202,500
TOTAL CAPITAL COST	\$6,000,000

In Section F.3, page 50, the applicant states that there are no start-up or initial operating expenses, as this is not a new service.

Availability of Funds

In Section F.2, pages 48-49, the applicant states that the project will be financed with accumulated reserves or owner's equity of OBH. Exhibit 7 contains a Certificate of Financial Commitment, dated June 15, 2017, and signed by the President of OBH which states:

"...OBH will commit \$6,000,000 in accumulated reserves to complete the proposed replacement and relocation of one linear accelerator."

Exhibit 8 contains a copy of Vidant Health's Consolidated Financial Statements for the years ended September 30, 2016 and September 30, 2015. The balance sheet indicates that as of September 30, 2016, Vidant Health had cash and cash equivalents of \$79,739,000, total assets of \$2,049,081,000 and total net assets of \$806,497,000 (total assets – total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for OBHCC's radiation therapy services (Section Q, Form F.4), the applicant projects that the revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below:

OBHCC Radiation Therapy Services

	OY1 FFY2020	OY2 FFY2021	OY3 FFY2022
Projected # of Treatments	3,088	3,116	3,144
Projected Average Charge (Gross Patient Revenue / Projected # of Treatments)	\$ 1,469	\$ 1,498	\$ 1,528
Gross Patient Revenue	\$ 4,535,329	\$ 4,667,670	\$ 4,803,872
Deductions from Gross Patient Revenue	\$ 2,415,198	\$ 2,485,674	\$ 2,558,205
Net Patient Revenue	\$ 2,120,131	\$ 2,181,996	\$ 2,245,667
Other Revenue	\$ 0	\$ 0	\$ 0
Total Revenue	\$ 2,120,131	\$ 2,181,996	\$ 2,245,667
Total Expenses	\$ 1,914,068	\$ 1,946,131	\$ 1,978,949
Net Income	\$ 206,063	\$ 235,865	\$ 266,718

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicant adequately demonstrates the financial feasibility of the project is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges) and operating costs. Therefore, the application is conforming to this criterion.

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

C

The applicant, The Outer Banks Hospital, Inc. (OBH) proposes to replace an existing linear accelerator and relocate it from a leased building to a new building, The Outer Banks Hospital Cancer Center (OBHCC), across the street from the existing hospital.

On page 125, the 2017 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 134 of the 2017 SMFP, Dare County is included in Linear Accelerator Service Area 28, which also includes Camden, Chowan, Currituck, Gates, Pasquotank, Perquimans and

Tyrrell counties. Providers may serve residents of counties not included in their service area.

There are two existing linear accelerators in Linear Accelerator Service Area 28. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 130, of the 2017 SMFP.

	Linear Accelerators	Total ESTV Procedures	Average ESTV Per Linear Accelerator
Albemarle Health: A Vidant Partner in Health	1	4,666	4,666
The Outer Banks Hospital, Inc.	1	3,095	3,095

The applicant proposes to replace and relocate its one existing linear accelerator at OBHCC within Dare County. Therefore, the applicant does not propose to increase the inventory of linear accelerators in the service area and no new services will be offered. The applicant adequately demonstrates the need to replace the existing linear accelerator at OBHCC and relocate it to a new building across the street from OBH. The discussion regarding the need for the replacement and relocation of the linear accelerator found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Therefore, the application is conforming to this criterion.

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

C

In Section Q, Form H, the applicant provides the historical and projected staffing for the radiation therapy services at OBHCC, summarized as follows:

**OBHCC
 Historical and Projected Staffing
 Radiation Therapy Services***

Position	Current Number of Full-Time Equivalent (FTE) Positions FY2016	Total Projected Number of FTE Positions OY2, FY2022
Registered Nurses (RNs)	0.8	0.8
Receptionist/Patient Registration	1.0	1.0
Radiation Therapists	2.3	2.3
Dosimetrist**	0.5 [0.0]	0.5 [0.0]
Physicist**	0.4 [0.0]	0.4 [0.0]
Total***	5.0 [4.1]	5.0 [4.1]

*The Project Analyst’s corrections are in brackets.

**The applicant states in Section Q, Form H, that the Dosimetrist and the Physicist are contractual positions.

***The applicant includes the FTE positions for Dosimetrist and Physicist in its calculation of total FTE positions, however the applicant’s salaried positions are equivalent to 4.1 FTEs only.

In Section Q, Form H, the applicant provides its staffing-related assumptions. The applicant states, in Form H, that the radiation therapy services include management by senior clinical personnel at OBH, however their responsibility for the radiology therapy services represents an extremely small portion of their management responsibilities. Therefore, the applicant states it does not include FTEs for the senior clinical personnel who have management responsibility for the proposed service. In addition, in Section H.4, page 60, the applicant states that it currently provides and will continue to provide physician coverage for the radiation therapy services under a professional services agreement with Vidant Medical Group. The applicant states it has a professional services agreement with one physician and does not anticipate any changes in the level of physician coverage upon completion of the project. The applicant states, in Section H.4, page 60, that Dr. Charles Shelton is the current medical director for the OBHCC radiation therapy services and that he will continue to serve in that capacity upon project completion.

In Section H.2, page 58, the applicant provides a listing of its recruitment methods, including aggressive advertising campaigns, enhanced employee referral program, utilization of search engine marketing and others. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. 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

In Section I.1, page 62, the applicant lists the necessary ancillary and support services for radiation therapy services which include: pathology services, pharmacy, radiology, oncology clinic services and respiratory therapy services. On page 62, the applicant states that all necessary ancillary and support services for radiation therapy services will continue to be available, and even more accessible, with the relocation of the linear accelerator. In Section I.2, page 62, the applicant states that it has long served Dare County and its surrounding communities and thus, has many longstanding, established relationships with local health care providers, including home healthcare and hospice agencies, long term care facilities, cancer support groups, social services, primary care providers and many others. Exhibit 14 contains copies of letters from physicians indicating support for the proposed project. The applicant adequately demonstrates that the necessary ancillary and support services are and will continue to be available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

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

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person

proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to replace and relocate an existing linear accelerator to a newly constructed building located across from OBH. The applicant states, in Section C.1, page 27, that the vault for the linear accelerator will be 1,071 square feet which will be part of a 4,598 square foot building. The applicant provides line drawings for the proposed project in Exhibit 5. Exhibit 10 contains the architect's certified cost estimate for the proposed project prepared by the Vice President for Vidant Health's Facilities & Properties. The certified cost estimate indicates that the design and construction costs will be \$2,346,000, which corresponds to the sum of the architect/engineering and construction contract costs listed in Form F:1a in Section Q of the application. In Section K.4, page 66, the applicant describes the methods that will be used by the facility to maintain efficient energy operations, including water conservation, and to contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. 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 L.1(b), page 71, the applicant provides the following payor mix for OBHCC's radiation therapy services for FY2016:

**OBHCC
 FY2016**

Payor Category	Radiation Therapy Services as Percent of Total
Self Pay	0.8%
Charity Care	1.2%
Medicare	50.6%
Medicaid	6.0%
Commercial Insurance	39.8%
TriCare	1.6%
Total	100.0%

As shown in the table above, the applicant states that 6.0% of its radiation therapy services were reimbursed by Medicaid and 50.6% were reimbursed by Medicare in FY2016.

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

Percent of Population						
County	% 65+	% Female	% Racial and Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
2014 Estimate	2014 Estimate	2014 Estimate	2014 Estimate	2010-2014	2010-2014	2014 Estimate
Dare	19%	51%	12%	11%	10%	20%
Currituck	15%	50%	13%	11%	8%	18%
Statewide	15%	51%	36%	17%	10%	15%

<http://www.census.gov/quickfacts/table> Latest Data as of 12/22/15

*Excludes "White alone" who are "not Hispanic or Latino"

***This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant’s current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal

assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L.2(b), page 71, the applicant states:

“OBH is obligated to provide care, regardless of race, color, creed, age, sex, national origin, religion, disability status, sexual preference, [sic] ability to pay for care.”

In Section L.2(c), page 72, the applicant states that no civil rights access complaints have been filed against OBH within the last five years. The application is conforming to this criterion.

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

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In Section L.3, page 72, the applicant projects the following payor mix for radiation therapy services at OBHCC during the second operating year, FY2021, summarized as follows:

**OBHCC
FY2021**

Payor Category	Radiation Therapy Services as Percent of Total
Self Pay	0.8%
Charity Care	1.2%
Medicare	50.6%
Medicaid	6.0%
Commercial Insurance	39.8%
TriCare	1.6%
Total	100.0%

On page 73, the applicant states that the proposed project's projected payor mix will approximate the historical payor mix for radiation therapy services at OBHCC.

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

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

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In Section L.5, page 73, the applicant states that radiation therapy services will be available through referral from a physician or other health care provider. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section M.1, page 74, the applicant states that it has extensive existing relationships with health professional training programs, including with Vidant Medical Group, Pitt Community College, Dare County Board of Education, and Winston-Salem State University. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

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The applicant, OBH, proposes to replace an existing linear accelerator and relocate it from a leased building to a new building, OBHCC, across the street from the existing hospital.

On page 125, the 2017 SMFP states, “A linear accelerator’s service area is the linear accelerator planning area in which the linear accelerator is located. Linear accelerator planning areas are the 28 multi-county groupings shown in Table 9I.” In Table 9I, page 134 of the 2017 SMFP, Dare County is included in Linear Accelerator Service Area 28,

which also includes Camden, Chowan, Currituck, Gates, Pasquotank, Perquimans and Tyrrell counties. Providers may serve residents of counties not included in their service area.

There are two existing linear accelerators in Linear Accelerator Service Area 28. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerators, as summarized from Table 9G, page 130, of the 2017 SMFP.

	Linear Accelerators	Total ESTV Procedures	Average ESTV Per Linear Accelerator
Albemarle Health: A Vidant Partner in Health	1	4,666	4,666
The Outer Banks Hospital, Inc.	1	3,095	3,095

In Section N.1, pages 75-76, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

“OBH is uniquely positioned to support the efficient integration of community health care services, while maintaining the highest standards of patient care.

...

OBH will use the proposed new linear accelerator to enhance the operational efficiency of radiation therapy services and to increase patient access – particularly for patients who today cannot receive services due to technology limitations.”

See also Sections C, D, H, K, L, N and O where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

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

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criterion (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussions regarding quality found in Criteria (1) and (20) are incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (1) and (13) are incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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Exhibit 8, page 3 of the Consolidated Financial Statements for Vidant Health, one of the parent companies of OBH, provides a listing of the healthcare facilities owned, managed or leased by Vidant Health in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision, two facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, both facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 10 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA