

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 24, 2017

Findings Date: March 24, 2017

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: Q-11292-17

Facility: Vidant Radiation Oncology Center at Vidant Medical Center

FID #: 170020

County: Pitt

Applicant: Vidant Radiation Oncology, LLC

Project: Relocate five existing linear accelerators, two from NC Radiation Therapy-Greenville and three from Leo Jenkins Cancer Center (replacing four) to a new outpatient cancer center at Vidant Medical Center which is currently under construction for a total of five linear accelerators upon project completion

### 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, Vidant Radiation Oncology, LLC (VRO), proposes to relocate five existing linear accelerators, two from NC Radiation Therapy - Greenville (NCRT-G) and three from Leo Jenkins Cancer Center (LJCC) to a new outpatient cancer center at Vidant Medical Center (VMC) which is currently under construction. VRO will own and operate the five linear accelerators as a freestanding radiation oncology center at Vidant Radiation Oncology Center at Vidant Medical Center (VROC at VMC) in 34,570 square feet of leased space in the cancer center tower at VMC. In addition, VRO proposes to replace four of the five linear accelerators, including the CyberKnife, during the relocation. NCRT-G is located at 801 W.H.Smith

Boulevard. LJCC is located at 600 Moye Boulevard, adjacent to VMC. All three facilities are located in Greenville, Pitt County.

### **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.

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 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.”*

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, page 20, the applicant states:

*“The proposed project involves replacing existing linear accelerators and relocating them to new leased space in the new VMC cancer center that is currently under construction and scheduled to open March 2018 (CON Project ID #: Q-10068-12). The proposed project involves approximately \$1.5 million in upfit design and construction to accommodate the new technology. However, the new cancer center at VMC, where the replacement linear accelerators will be located, is being constructed in accordance with the representations made in its Certificate of Need application to*

*ensure energy efficiency and cost effective utilizes, including water conservation. In addition, the proposed replacement linear accelerator [sic] are state-of-the-art and designed for modern [sic] energy efficiency standards.”*

In Section K.4(c), page 74, the applicant states:

*“VRO will closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations.*

*More generally, all Vidant facilities, including VRO, are committed to energy efficiency and sustainability, including water conservation, that balances the need for healthcare services and environmental sustainability in the communities served. In this regard, Vidant has several guiding principles:*

- 1. Implement environmental sustainability to improve and reduce the environmental impact.*
- 2. Integrate sustainable operational and facility best practices into existing and new facilities.*
- 3. Encourage partners to engage in environmentally responsible practices.*
- 4. Promote environmental sustainability at work, home and community.*
- 5. Deliver improved performance to provide a long-term return on investment that supports corporate mission and values.*

*The upfitting plans, though minor compared to the construction that has already occurred, will adhere to these principles.”*

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).

In summary, the application is consistent with Policy GEN-4, subject to Condition (4) of Criterion (4). Consequently, the application is 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.

In Section A.1 (e), page 5, the applicant states that VRO is a 50/50 joint venture limited liability company between Pitt County Memorial Hospital, Inc d/b/a VMC, a subsidiary of University Health Systems of Eastern Carolina d/b/a Vidant Health (VH) and North Carolina Radiation Therapy Management Services, LLC (NCRT), a subsidiary of 21<sup>st</sup> Century, Inc (21C). VRO was formed on January 1, 2016 for the purpose of owning and operating five linear accelerators, including a CyberKnife, in Greenville. In Section C.1, page 21, the applicant states:

*“The purpose of the formation of the joint venture was to consolidate and coordinate radiation oncology services in Pitt County to provide a more consistent, high quality, lower cost service to cancer patients in eastern NC.”*

In Section A, pages 7-9, the applicant describes the proposed project, stating that VRO proposes to replace and relocate four existing linear accelerators, including an existing CyberKnife, and relocate a fifth linear accelerator to the cancer center tower currently under construction at VMC. At project completion, all five linear accelerators will be relocated from their current two locations and consolidated into one new location in 34,750 square feet of leased space in the new VMC cancer center scheduled to open March 2018 (CON Project ID #Q-10068-12). VRO will continue to own and operate the linear accelerators as a freestanding radiation oncology center doing business as VROC at VMC in the leased cancer center space. VMC will continue to operate all other existing and new portions of the hospital facility.

### **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, Pitt County is included in Linear Accelerator Service Area 27, which also includes Beaufort, Bertie, Greene, Hertford, Hyde, Martin, and Washington counties. Providers may serve residents of counties not included in their service area.

The applicant currently operates five linear accelerators, including a CyberKnife, in two separate locations in Greenville. In Sections C.2 and C.3, pages 30-31, the applicant provides the current (January 1, 2016 – September 30, 2016) and projected (FFY2020-FFY2022) patient origin for VRO linear accelerator services, as summarized in the table below.

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

<b>County</b>	<b>Current (1/1/16-9/30/16)* Percent of Total Patients</b>	<b>Projected (FFY2020-FFY2022) Percent of Total Patients</b>
Pitt	36.3%	36.3%
Edgecombe	8.1%	8.1%
Martin	7.0%	7.0%
Lenoir	6.4%	6.4%
Beaufort	6.2%	6.2%
Bertie	3.6%	3.6%
Onslow	3.4%	3.4%
Hertford	2.9%	2.9%
Nash	2.6%	2.6%
Wilson	2.5%	2.5%
Duplin	2.2%	2.2%
Wayne	2.2%	2.2%
Greene	2.2%	2.2%
Other (<2% of total)	14.6%	14.6%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>

\*Nine months of data in FY16 after VRO began operations on January 1, 2016  
 Totals may not sum due to rounding

The applicant does not identify the counties that make up “Other”. The 2017 License Renewal Application (LRA) and 2017 Registration and Inventory of Medical Equipment (RIME), submitted for the linear accelerators involved in this review included patient origin for patients treated in 2016 and showed “Other” includes a few patients from the counties of Brunswick, Carteret, Chowan, Craven, Cumberland, Dare, Gates, Halifax, Hyde, Jones, North Hampton, Pamlico, Pender, Perquimans, Person, Tyrell, Warren, Washington and other states. In Section C.3(c), page 31, with regard to the assumptions for projected patient origin, the applicant states:

*“VRO assumes future patient origin will not be significantly impacted by the proposed project and is assumed to be approximate to historical distributions.”*

The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section C.1, pages 22-28, the applicant discusses radiation therapy services, the different types of procedures performed on linear accelerators, the replacement equipment it proposes, its construction and capital requirements, staffing needs and the projected timeline for completion of the project. Beginning on page 32 of Section C.4, the applicant discusses cancer as a disease, its incidence and mortality rates in the VRO service area, VRO’s and VH’s initiatives to fight against cancer in eastern North Carolina, and radiation therapy as one of the most important components of the cancer treatment process, resulting in the applicant’s statement on page 35:

*“Therefore, VRO must maintain the latest state-of-the-art technology and services related to radiation therapy.*

*However, except for LinAc #5, which is a new unit that was recently installed to replace an older unit per CON Project ID #Q-11116-15, each of the other linear accelerator units owned and operated by VRO are at least 8 years old, with one unit approaching 20 years old. Additionally, since 2013, Siemens, the manufacturer of LinAc #3, is no longer manufacturing or servicing linear accelerators and therefore, it has become increasingly difficult to find spare parts when the unit needs servicing, to find qualified individuals to provide routine maintenance and servicing, and to find ongoing technical training opportunities. Also, the four older units cannot provide the same services and treatments that new technology can. In addition, operating in two different locations has created operational inefficiencies and redundancies (cost effectiveness issues) as well as patient confusion and inconvenience (access issues).”*

Per the applicant in Section C.1, page 29 of the application, and information in VRO’s 2017 RIME, the following table identifies the linear accelerators involved in this project, their current and proposed locations and specifications.

	Linac #1	Linac #2	Linac #3	Linac #4	Linac #5 (Before 2016 Replacement)
<b>Existing Equipment</b>					
Vendor	Varian	Varian	Siemens	Accuray	Varian (Siemens)
Model	Clinac 2100	Clinac 2100	Primus	CyberKnife	TrueBeam (Oncor)
Serial #	1214	1167	3756	192	2815 (5385)
Current Location	NCRT	NCRT	LJCC	LJCC	LJCC
Year of Purchase	1998	2008	2003	2008	2016 (2008)
<b>Proposed Project</b>					
Proposal	Replace/Relocate	Replace/Relocate	Replace/Relocate	Replace/Relocate	Relocate Only
Phase of Project	Phase 1	Phase 1	Phase 2	Phase 1	Phase 1
Proposed Location / Vault	VROC at VMC Vault #1	VROC at VMC Vault #2	VROC at VMC Vault #5	VROC at VMC Vault #4	VROC at VMC Vault #3
Proposed Vendor	Varian	Varian	Varian	Accuray	See Current Above
Proposed Model	Edge	TrueBeam	TrueBeam	M6 CyberKnife	See Current Above

In Section C.4, pages 36-44, the applicant further discusses the need for the proposed project and describes the factors which it states support the need for the proposed equipment replacement and relocation, including the following:

- Need for local care (pages 36-37) – The applicant states that the average cancer patient will receive 25-30 radiation therapy treatments during the course of his/her treatment; therefore, having access to those services close to where a patient lives is pivotal in the cancer treatment process. The applicant states that hospital LRAs show that 445

radiation oncology patients from VRO's service area (16.1%) left the area for radiation oncology treatment services, based on Figure C.4.4 on page 37.

- Age and technology limitations of the existing units (pages 37-39) – The applicant states that all of the existing linear accelerators, except for the newly replaced one, are “old, out of date, and cannot provide the same level of services with the same accuracy, options, and speed newer units can provide.” In addition, the applicant states:
  - Siemens no longer manufactures or services its units and it is difficult to find spare parts or a qualified individual to provide routine maintenance and servicing.
  - The Primus unit does not have reliable CT-image guidance and has poor quality imaging that is nearly impossible to interpret, compromising quality of care.
  - None of the linear accelerators being replaced has VMAT technology, which significantly improves the quality of IMRT, allowing for more conformal, homogenous and normal-tissue sparing plans for delivery, improving both the target volume coverage and reducing the acute and late toxicity.
  - None of the older linear accelerators have any form of tumor motion management, breath hold or other technologies for improving accurate treatment delivery and target volume coverage.
  - VRO must sometimes refer patients to UNC-Chapel Hill and Duke University when treatment plans cannot be produced with adequate quality.
  - Downtime is an issue with older units, placing undo stress on the operational units, delaying treatments and sometimes causing patients to travel to another facility for treatment.
  - All of the proposed radiotherapy treatment equipment represent the latest technologies to provide substantially better radiation treatment with more accuracy and less toxicity. These capabilities are unavailable on the current units. The applicant states that the acquisition of the proposed state-of-the-art radiation treatment technologies will dramatically enhance the quality, safety, efficacy, accuracy and speed of all the radiation treatments and will allow VRO to treat more patients better, faster and with more reliability.
- Operational inefficiencies (pages 39-40) – as discussed earlier, the five existing linear accelerators, including a CyberKnife, are in two separate locations in Greenville, NC. The applicant states that operating two locations has created operational inefficiencies and redundancies as well as causing patient confusion and inconvenience, specifically:
  - Maintaining all expenses related to two physical locations; duplicate costs for rent, utilities, housekeeping, laundry, maintenance, insurance, etc.
  - Maintaining duplicate administrative and support staff in both locations.
  - Duplication and redundancy makes it impossible to provide the most cost efficient care and ultimately drives up health care costs.
  - Patients are routinely confused about which location to go to for their treatments and wind up presenting at the wrong location. Travel between the two locations is not easy or convenient and this causes patients to be late for appointments

- and can cause backlogs for appointments that follow, delaying other patients' treatments.
- Co-location of radiation oncology services into one location at VMC's new cancer center will dramatically enhance the cost efficiency and patient access associated with the provision of radiation therapy services. VRO patients will also have proximal access to all of the other wellness services VMC provides, such as cancer education classes, cancer screening events, oncology clinics, chemotherapy services, surgical oncology services, and inpatient services.
  - Current and projected demand (pages 40-44) – as discussed by the Project Analyst below.

Projected Utilization

In Section C.4 of the application, pages 40-41, and Form C, the applicant provides tables showing the historical and projected utilization for the VRO linear accelerators through the first three years of operation following completion of the project (FY2020-FY2022), which is summarized below.

**VROC at VMC  
Historical and Projected Linear Accelerator Treatments  
FY2014-FY2022**

<b>Fiscal Year</b>	<b>Treatments</b>	<b>Patients</b>
2014 Actual	22,882	1,105
2015 Actual	21,879	1,063
2016 Actual	19,718	1,011
2017 Interim	20,033	1,033
2018 Interim	20,354	1,055
2019 Interim	20,680	1,077
2020 (PY 1)	21,011	1,100
2021 (PY 2)	21,347	1,124
2022 (PY 3)	21,688	1,148

In Section C.4, pages 41-44, the applicant describes its assumptions and methodology for projecting utilization of the VRO linear accelerators. The applicant describes the assumptions with regard to historical and future utilization as follows:

*“Even though historical treatment and patient volumes declined from FY14 through FY16, VRO believes that future treatment volumes will increase on average 1.6% per year at least through FY22 (third year following project completion).”*

As shown in the table above, the applicant's utilization projections are based on the historical utilization of VRO's existing linear accelerators, projected forward with an annual increase of 1.6%. On page 41, the applicant states that VH, and by extension VRO, utilizes Sg2 Analytics' procedure-based forecasting tool to project demand for radiation therapy. The applicant further states that Sg2's forecasting model incorporates population growth, disease incidence, demographic composition, payor and regulatory changes, model of care shifts, and technology



advancements. The Sg2 forecast (Figure C.4.6, page 42) shows radiation oncology treatments will increase on average 1.6% per year over the next 10 years.

To further add support to its projected utilization increase, as the applicant states on page 37 and is discussed in the Findings above, hospital LRAs show that 445 radiation oncology patients from VRO's service area (16.1%) left the area in 2016 for radiation oncology treatment services.

If by FY2022, VRO recovers one quarter of the 445 radiation therapy patients that have historically left the service area for treatment, VRO would be treating an additional 111 ( $445 \times 0.25$ ) patients.

In addition, in Figure C.4.7 on page 43 of the application, the applicant provides data projecting that there are on average 479 newly diagnosed cancer cases each year that could be treated with radiation therapy but are not receiving radiation therapy treatment. On pages 43-44, the applicant states:

*“VRO believes access, education and technology limitations are causing the disparity. As stated above, VH and all its subsidiaries, and NCRT are committed to investing dollars and resources to fight against cancer in eastern North Carolina. VRO believes that through developing more aggressive education and screening programs designed to diagnose cancer earlier on in the disease progression, more people will know about and have access to radiation oncology services. VRO believes that it can reach the vast majority of these patients in the future through its aggressive education and screening programs. Success in this will identify more cancer patients earlier on in the disease progressions and treatments services like radiation oncology will become more of an option. This will in turn increase the demand for radiation oncology treatments.”*

If by 2022, VRO reaches only one quarter of those new cancer cases, identified above as potentially benefitting from radiation therapy but failing to receive such treatment, the number of patients receiving radiation treatments at VRO by the third year of operation could increase by 120 ( $479 \times 0.25$ ) patients. With the additional 111 patients staying in the service area for treatment and the 120 new cancer patients reached through education, VRO's total number of patients receiving radiation therapy by FY2022 could reach 1,379 ( $1,148 + 111 + 120$ ), which equates to 276 ( $1,379/5$ ) patients per linear accelerator. This exceeds the minimum performance standard of 250 patients required in 10A NCAC 14C .1903(a)(2). Exhibit 15 contains letters from physicians in the proposed service area expressing support for the proposed project and their intention to refer patients to the proposed service. Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire and relocate replacement linear accelerators.

### **Access**

In Section C.10, page 46, the applicant states:

*“Because of its association with Vidant Medical Center, VRO has an obligation to accept any patient requiring medically necessary treatment.”*

On page 47, the applicant affirms VRO’s continued commitment to provide services to all patients, from all races, regardless of sex, age, handicapped status, socioeconomic status, or ability to pay. In Section L.3, page 81, the applicant projects that 59.8 percent of patients to be served 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 C.5, pages 44-45 and Section D.2, pages 51-54, the applicant discusses VRO’s relocation of radiation therapy services to VMC’s cancer center. Currently, VRO owns and operates five existing linear accelerators in two separate locations, two at NCRT-G and three, including a CyberKnife at LJCC. At the completion of the project, all five linear accelerators will be relocated from their existing locations and consolidated into one new location in leased space in the new VMC cancer center, which is physically adjacent to the existing LJCC and 0.3 miles from the existing NCRT-G facility. The applicant states that VRO’s ability to meet the needs of the patients currently utilizing VRO’s radiation oncology services will *“only be enhanced by the proposed project through the reduction of operational inefficiencies and redundancy (cost efficiency) and elimination of patient confusion and inconvenience (improved access).”* In addition, the applicant states that having the radiation therapy services located inside VMC’s new cancer center, will provide radiation oncology patients with onsite access to all the other oncology services VMC provides.

In Section L.3, the applicant projects 59.8% of its services will be provided to Medicare and Medicaid recipients, stating that the proposed payor mix for VROC at VMC approximates the historical payor mix at VRO. 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 relocation of the radiation therapy services to VMC 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 VRO will be adequately met following the proposed relocation of the linear accelerators and radiation therapy services from NCRT-G and LJCC to VROC at VMC. Therefore, the application is conforming to this criterion.

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

#### CA

In Section E.2, page 55, 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 option of maintaining the status quo was rejected immediately because it would not be in the best interest of the cancer patients in the community. The applicant states that maintaining aging equipment in two locations is not an effective alternative because it is operationally inefficient, ineffective, creates redundancies, leads to a higher cost of care and perpetuates access issues for patients.
- Relocate Existing Equipment without Replacement – The applicant states that continuing to use out dated equipment that is near or past its useful life is not the high standard of quality of care needed to effectively treat and cure cancer; therefore, this alternative was rejected.
- Project as Proposed – The applicant states that this option, though more costly from an initial capital perspective was determined to be the only alternative to pursue in terms of providing the residents of eastern North Carolina with access to affordable, high quality, convenient, effective, state-of-the-art radiation oncology services.

After considering the above alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

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. Vidant Radiation Oncology, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Vidant Radiation Oncology, LLC shall acquire no more than four linear accelerators, including a CyberKnife, to replace four of the existing five linear accelerators being relocated to Vidant Radiation Oncology Center at Vidant Medical Center. The applicant shall dispose of the four existing linear accelerators being replaced by removing them from North Carolina.**
  3. **Vidant Radiation Oncology, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section F of the application and that would otherwise require a certificate of need.**
  4. **Vidant Radiation Oncology, LLC 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. **Vidant Radiation Oncology, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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:

**VRO Linear Accelerator Project Capital Cost**

Construction/Renovation Costs	\$1,300,000
Architect Fees	\$200,000
Medical Equipment	\$20,559,225
Financing (Equip Lease Interest)	\$1,850,739
Existing Unit Relocation	\$250,000
<b>TOTAL CAPITAL COST</b>	<b>\$24,159,964</b>

Source: Section Q, Form F.1a: Capital Cost

Exhibit 2 contains the equipment quotes and specifications for the replacement linear accelerators. Exhibit 3 contains the line drawings illustrating the location of the vaults. Exhibit 11 contains a letter from the architect that estimates the total project cost, including the linear accelerator replacements, at \$24,159,964. Exhibit 12 contains the lease agreement between the hospital and VRO for the leased space in the VMC cancer center.

In Section F.3, page 58-59, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

### **Availability of Funds**

In Section F.2, page 56, the applicant states that VRO will fund \$1,937,770 of the project capital costs and \$22,222,194 will be funded by loans secured by VMC. On page 57, the applicant states:

*“Since VRO is a relatively new joint venture, VMC, a member of VRO [sic] has agreed to secure and guarantee a capital lease for the purchase of the three replacement linear accelerators and the replacement CyberKnife. VRO will repay the capital lease through normal operations, but VMC has agreed to make the necessary payments in the event VRO cannot meet the obligation.”*

The applicant further states that VMC will commit funds to VRO through a “*capital call*” and VRO will then use those contributed funds to pay for the upfit design and construction costs, additional minor equipment not included in the capital lease, and the relocation of the newly upgraded fifth linear accelerator.

In Exhibit 7, the applicant provides a letter dated December 15, 2016, from Bank of America offering a lease financing proposal to VH for the equipment in the amount of \$20,371,455. Exhibit 7 also contains a letter dated January 16, 2017 from VH Chief Financial Officer, documenting VH’s intent to secure and guarantee the capital lease for \$20,371,455 for the replacement and relocation of the four linear accelerators, including the CyberKnife. Exhibit 8 contains the consolidated financials of VH for the years ended September 30, 2016 and 2015, documenting cash and cash equivalents of \$79,739,000, total current assets of \$515,376,000 and total net assets of \$931,279,000 (total assets – total liabilities), as of September 30, 2016. Exhibit 7 contains a letter dated January 7, 2017 from the Vice President of VRO and Chief Strategic Service Line Development Officer for VH, documenting VRO’s commitment to pay the capital lease payments out of normal operations for the proposed project. Exhibit 9 contains VRO’s balance sheet, as of September 30, 2016, showing \$3 million in cash, \$2 million in retained earnings, and \$28 million in total equity (total assets – total liabilities).

The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

### **Financial Feasibility**

In the pro forma financial statements for VRO’s radiation therapy services (Section Q, Form F.3), the applicant projects that the radiation therapy operating expenses will exceed revenues in each of the first three years of the project, as shown in the table below.

**VRO Radiation Therapy Services**

	<b>Project Year 1 FFY2020</b>	<b>Project Year 2 FFY2021</b>	<b>Project Year 3 FFY2022</b>
Projected # of Treatments	21,011	21,347	21,688
Projected Average Charge (Gross Patient Revenue / Projected # of Treatments)	\$ 2,706	\$ 2,760	\$ 2,815
Gross Patient Revenue	\$ 56,850,411	\$ 58,915,218	\$ 61,055,019
Deductions from Gross Patient Revenue	\$ 37,247,507	\$ 38,600,337	\$ 40,002,301
Net Patient Revenue	\$ 19,602,904	\$ 20,314,881	\$ 21,052,718
Other Revenue	\$ 5,853	\$ 5,853	\$ 5,853
Total Revenue	\$ 19,608,756	\$ 20,320,734	\$ 21,058,570
Total Expenses	\$ 21,505,328	\$ 21,797,823	\$ 22,098,874
Net Income	\$ (1,896,571)	\$ (1,477,089)	\$ (1,040,304)

The applicant also provides VRO's EBIDTA on Form F.3: \$2,746,278, \$3,165,761 and \$3,602,546 for FFY2020 through FFY2022, respectively. EBIDTA (earnings before interest, tax, depreciation and amortization) is also called operational cash flow and is a measure of a company's operating performance and profitability. The noncash expense of the depreciation on the linear accelerator equipment alone reduces VRO's net income by \$4.5 million (Form F.3) in each of the first three project years, even though, there is not a related cash payment for the depreciation expense recorded during those periods.

Furthermore, as the applicant discusses in Section F.2(b), page 57, VMC is securing and guaranteeing the capital lease for the purchase of the linear accelerators and has agreed (as documented by VH letter dated January 16, 2017, in Exhibit 7) to make VRO's necessary capital lease payments in the event VRO cannot meet the obligation. Section Q, Form F.3 shows the capital lease principle and interest expense to be \$3.7 million in each of the first three project years; therefore, VRO's income net of the capital lease principle and interest payments would be approximately \$2 million each year. As discussed above and documented in Exhibit 8, VH has adequate funds to cover VRO's lease obligation, as well as any other operating needs.

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

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

C

The applicant proposes to relocate five existing linear accelerators (replacing four) from two separate locations in Greenville to the cancer center at VMC.

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, Pitt County is included in Linear Accelerator Service Area 27, which also includes Beaufort, Bertie, Greene, Hertford, Hyde, Martin, and Washington counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 27. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerator, as summarized from Table 9G of the 2017 SMFP.

	<b>Linear Accelerators</b>	<b>Total ESTV Procedures</b>	<b>Average ESTV Per Linear Accelerator</b>
Vidant Beaufort Hospital	1	2,383	2,383
Vidant Roanoke-Chowan Hospital	1	2,616	2,616
Leo Jenkins Cancer Center	2	10,136	5,068
NC Radiation Therapy - Greenville	2	9,437	4,719
Vidant Medical Center (CyberKnife)	1	2,097	2,097

Source: 2017 SMFP, Table 9G, page 130. The 2017 SMFP does not reflect the formation of VRO in 2016 to own and operate all five Vidant linear accelerators, including the VMC CyberKnife, which was moved to LJCC.

The applicant proposes to relocate the five VRO linear accelerators, replacing four, to VROC at VMC. 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 states the existing linear accelerator equipment being replaced has reached the end of its useful life, has become increasingly unreliable, and does not have the capabilities necessary to meet the current standard of care. The applicant also states that relocating the five accelerators from the two separate locations to the VROC at VMC cancer center will allow VRO to provide more efficient and cost effective services, while providing its patients with better access to cancer services. The applicant adequately demonstrates the need to replace four existing linear accelerators and relocate all five existing linear accelerators to the VROC at VMC cancer

center. The applicant adequately demonstrates that the projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved linear accelerator services in Linear Accelerator Service Area 27. 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 H, page 65, the applicant references Section Q: Form H for the historical and projected staffing and related assumptions. VRO currently employs 37.0 full-time equivalent (FTE) positions to staff the linear accelerator services at the two current locations, and VRO does not project any changes to staffing associated with the proposed project. Exhibit 10 contains a copy of a letter from the Radiation Oncology Department Chair at Brody School of Medicine, East Carolina University and Medical Director for Vidant Radiation Oncology, expressing support for the proposed project. Exhibit 15 of the application contains copies of letters from other physicians expressing support for the proposed project. 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 69, the applicant describes the necessary ancillary and support services for radiation therapy and states that it currently provides all the necessary ancillary and support services and will continue to provide the needed services. Exhibit 15 contains letters of support from physicians. The applicant states that while VRO is a new entity, its component parts, VMC, NCRT and the radiation oncology staff at East Carolina University all have long standing, established relationships with local health care providers and community outreach programs. 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 existing linear accelerators to 34,570 square feet of leased space in VMC's new cancer center tower scheduled to be completed in March 2018 (Project ID #Q-10068-12). As part of the previously approved project, VMC is constructing the basic infrastructure for the vaults and related patient and support space. Most of the "upfit" costs for this proposed project consists of the necessary construction needed to make the vaults meet the design and mechanical specifications for the specific linear accelerators which will be relocated to the center. The line drawings are provided in Exhibit 3. Exhibit 11 contains the architect's certified cost estimate prepared by Vidant Health's Chief Facilities & Properties Officer. In Section K.4, pages 74-75, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and 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 79, the applicant reports the following payor mix for VRO's radiation therapy services for FY2016:

<b>Payor Category</b>	<b>Radiation Therapy Services as Percent of Total</b>
Self Pay	3.4%
Charity Care	1.9%
Medicare	51.6%
Medicaid	8.2%
Commercial Insurance	27.2%
TriCare	0.7%
Other (Hospice)	7.0%
<b>Total</b>	<b>100.0%</b>

As shown in the table above, the applicant states that 8.2% of its radiation therapy services were reimbursed by Medicaid and 51.6% were reimbursed by Medicare.

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
Pitt	11%	53%	44%	23%	8%	18%
Beaufort	22%	52%	34%	19%	14%	20%
Bertie	20%	50%	65%	28%	14%	17%
Greene	15%	46%	52%	28%	15%	22%
Hertford	18%	51%	66%	26%	16%	17%
Hyde	18%	45%	39%	22%	10%	23%
Martin	21%	53%	48%	20%	12%	17%
Washington	21%	53%	55%	27%	18%	17%
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 79, the applicant states:

*"With VMC being a member of VRO, VRO 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 80, the applicant states that no civil rights access complaints have been filed against VRO, or the members, VMC and NCRT, 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

C

In Section L.1(b), page 81, the applicant projects the following payor mix for VRO's radiation therapy services for FFY2021:

<b>Payor Category</b>	<b>Radiation Therapy Services as Percent of Total</b>
Self Pay	3.4%
Charity Care	1.9%
Medicare	51.6%
Medicaid	8.2%
Commercial Insurance	27.2%
TriCare	0.7%
Other (Hospice)	7.0%
<b>Total</b>	<b>100.0%</b>

On page 81, the applicant states:

*“VRO assumes that the proposed project will not have a significant impact on payer mix. Therefore, the future distribution of patients by payer is assumed to approximate the historical payer mix.”*

The applicant demonstrates that the medically underserved population 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 L.5, page 82, the applicant describes the range of means by which a person will have access to VRO's radiation therapy services, including by physician referral. 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.

C

In Section M.1, page 83, the applicant states that by virtue of its member, Vidant Medical Center, which is the academic medical center teaching hospital for the Brody School of Medicine at Eastern Carolina University, VRO already has extensive relationships with health professional training programs. On page 83, the applicant provides a list of educational institutions with which VRO and VMC have training arrangements, including Brody School of Medicine at ECU, and the ECU Schools of Nursing, Allied Health Sciences, and Social Work, among others. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

C

The applicant proposes to relocate five existing linear accelerators, replacing four, to the VMC cancer center tower, which is currently under construction.

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, Pitt County is included in Linear Accelerator Service Area 27, which also includes Beaufort, Bertie, Greene, Hertford, Hyde, Martin, and Washington counties. Providers may serve residents of counties not included in their service area.

There are seven existing linear accelerators in Linear Accelerator Service Area 27. The following table identifies the provider, number of linear accelerators, and average utilization of each of the linear accelerator, as summarized from Table 9G of the 2017 SMFP.

	<b>Linear Accelerators</b>	<b>Total ESTV Procedures</b>	<b>Average ESTV Per Linear Accelerator</b>
Vidant Beaufort Hospital	1	2,383	2,383
Vidant Roanoke-Chowan Hospital	1	2,616	2,616
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NC Radiation Therapy - Greenville	2	9,437	4,719
Vidant Medical Center	1	2,097	2,097

Source: 2017 SMFP, Table 9G, page 130. The 2017 SMFP does not reflect the formation of VRO in 2016 to own and operate all five Vidant linear accelerators, including the CyberKnife, which was moved to LJCC.

The applicant proposes to relocate five existing linear accelerators, replacing four, including the CyberKnife, to the cancer center at VMC. In Section N.1, pages 85-86, 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:

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

The applicant lists examples of how VRO will accomplish the above on page 85.

See also Sections B, C, E, F and H 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 Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussions regarding access found in Criteria (3) 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.

In Section O.1, pages 87-88, the applicant describes the methods used by VRO to insure and maintain quality care, fully discussing the following:

- Quality Improvement Plan,
- Utilization Review Plan,
- Risk Management Plan, and
- Maintaining accreditation status.

In Section O.3(a), pages 89-90, the applicant states that VRO does not own any other radiation therapy centers; however, in addition to VRO's facilities in Pitt County, NCRT manages/operates eleven 21<sup>st</sup> Century Oncology radiation therapy centers in Buncombe, Halifax, Haywood, Henderson, Macon, McDowell, Rutherford, Sampson, Transylvania and Wayne counties in North Carolina. In Sections O.3(b) and (c), the applicant states that all of the facilities listed in response to Section O.3(a) have been in continuous operation over the last 18 months and have provided quality services to their respective communities. The applicant further states that none of the facilities identified above have been determined by the Division of Health Service Regulation or the Centers for Medicare and Medicaid Services to have operated out of compliance with any Medicare Conditions of Participation during the 18-month look-back period.

In Section A.10, page 10, the applicant states that Vidant Health, the parent company of VMC, also owns and operates linear accelerators in Hertford, Beaufort, and Dare counties. None of the licensed health service facilities owned or operated by the applicant, or related entities, as identified by the applicant in Section A.10, page 10, or Section O.3(a), pages 89-90, have had their licenses revoked or had their Medicare or Medicaid provider agreements revoked. The information provided by the applicants is reasonable and supports the determination that the applicants are 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