

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 17, 2016

Findings Date: February 17, 2016

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: Q-11116-15

Facility: Leo Jenkins Cancer Center

FID #: 100878

County: Pitt

Applicants: NewCo Cancer Services, LLC

Vidant Radiation Oncology, LLC

Project: Replace a linear accelerator

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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.

C

The applicants, Vidant Radiation Oncology, LLC [**VRO**] and NewCo Cancer Services, LLC d/b/a Leo Jenkins Cancer Center [**LJCC**] propose to acquire a linear accelerator to replace one of their two existing linear accelerators located at 600 Moye Boulevard in Greenville (Pitt County). There are no need determinations in the 2015 State Medical Facilities Plan (SMFP) applicable to this review.

Policies

There is one policy in the 2015 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 \$2 million, but less than \$5 million. In Section III.2, pages 55-56, the applicants state

“The proposed replacement linear accelerator is state-of-the-art, designed for modern energy efficiency standards. ... LJCC and VRO have designed the proposed equipment replacement project to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2015 SMFP Policy GEN-4. The building codes apply to systems and equipment for electrical power, lighting, heating, ventilating, air condition service, energy management, water heating and water conservation. Water conservation design standards include the use of low-flow fixtures and low-flow toilets throughout the facility. The LJCC facility was constructed to ensure energy efficiency and cost effective utilities, including water conservation. LJCC and VRO will closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations.”

The applicants adequately demonstrate 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.

In summary, the application is consistent with Policy GEN-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.

C

The applicants, VRO and LJCC, propose to acquire a linear accelerator to replace one of the two existing linear accelerators at the Leo Jenkins Cancer Center located at 600 Moye Boulevard in Greenville. In Section I.11, page 8, the applicants state that LJCC is a 50/50 joint venture limited liability company whose members are East Carolina University Brody School of Medicine (ECU) and Vidant Medical Center (VMC). Also, on page 8, the applicants state,

“As of the filing date for this application (November 16, 2015), the sole member of VRO is NCRT [North Carolina Radiation Therapy Management Services, LLC]. Upon completion of the proposed project, the members of VRO will include VMC and NCRT.”

In Section I.12(e), page 14, the applicants state,

“As described previously in I.10, LJCC owns and operates two existing linear accelerators and CT simulator, pursuant to CON Project I.D. # Q-8562-10. VMC owns and operates a CyberKnife linear accelerator, which is operated as a freestanding radiation treatment service at LJCC, pursuant to CON Project I.D. Q-8558-10. North Carolina Radiation Therapy Management Services, LLC (NCRT) owns and operates two existing linear accelerators as part of NC Radiation Therapy-Greenville d/b/a 21st Century Oncology (21C).

First, VMC seeks to obtain full ownership of the two linear accelerators and CT simulators currently owned by LJCC. LJCC will continue to exist after VMC obtains 100% ownership of the linear accelerators and simulators. Once VMC obtains full ownership, the same equipment will be used to provide the same radiation oncology services, in the same location.

Second, as part of a joint venture, VMC and NCRT will be combining and contributing their existing freestanding radiation oncology services, medical equipment (including the five linear accelerators, one of which is a CyberKnife linear accelerator) and related assets to the newly created VRO. This ownership change is anticipated to occur on or around January 1, 2016. After the joint venture occurs, all of the equipment will continue to be operated in their existing locations. The only changes that will occur are the changes associated with ownership. The same equipment will be used to provide the same radiation oncology services, in the same location.”

In Section II.1(a), pages 19-20, the applicants describe the project as follows:

“The proposed replacement linear accelerator will be located in the same vault as the existing equipment, as shown in the site plan in Exhibit 9. The proposed project will include 1,246 square feet of basic renovations in the current radiation therapy department. Minor plumbing, mechanical and electrical renovations will also be made to accommodate the specifications of the new radiation therapy equipment and maintain compliance with current construction codes.”

Population to be Served

On page 125, the 2015 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 2015 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.

LJCC currently operates two linear accelerators. In Sections III.4 and III.5, pages 61-63, the applicants provide the current (FY2015) and projected (FY2017-FY2018) patient origin for linear accelerator services at LJCC, as summarized in the table below.

**LJCC Linear Accelerator Services
 Current and Projected Patient Origin**

County	Current (FY2015) Patient Origin Percent of Total Patients	Projected (FY2017-FY2018) Percent of Total Patients
Pitt	47.1%	48.1%
Beaufort	14.4%	12.5%
Edgecombe	10.1%	10.3%
Lenoir	4.1%	4.2%
Martin	3.9%	4.0%
Craven	3.4%	3.4%
Washington	3.2%	3.2%
Wilson	2.4%	2.5%
Bertie	2.1%	2.4%
Other*	9.3%	9.3%
TOTAL	100.0%	100.0%

Source: Tables on pages 61 and 63.

In Section III.5, page 64, with regard to the assumptions for projected patient origin, the applicants state, “The projected patient origin is generally consistent with LJCC historical experience providing linear accelerator services.” The applicants adequately identified the population proposed to be served.

Analysis of Need

In Section III.1(a) and (b) of the application, the applicants describe the factors which they state support the need for the proposed project, including:

- The existing linear accelerator is outdated technology and is increasingly unreliable, requiring downtime for maintenance and repairs (pages 36-39).
- The proposed replacement linear accelerator has state-of-the-art technology that will expand the treatment capabilities of LJCC and bring many benefits to the patients treated there (pages 39-42).
- The projected growth in the service area population age 65 and older (pages 43-45).
- Higher than average rates of cancer incidence for the service area population (pages 46-49).

Projected Utilization

In Section IV.1 of the application, pages 67-68, the applicants provide tables showing the historical and projected utilization for the LJCC linear accelerators through the first three years of operation following completion of the project (FY2017-FY2019), which is summarized below.

**Leo Jenkins Cancer Center
 Historical and Projected Linear Accelerator Utilization, FY2014-FY2019**

Fiscal Year	# of Units	Patients Treated	ESTV* Procedures	Patients Treated Per Unit	Percent Increase (Patients)	Percent of Minimum Performance Standard**
2014 Actual	2	535	10,773	268	---	107%
2015 Actual	2	541	10,129	271	1.1%	108%
2016 Interim	2	541	10,129	271	0.0%	108%
2017 (PY 1)	2	554	10,378	277	2.4%	111%
2018 (PY 2)	2	568	10,634	284	2.5%	114%
2019 (PY 3)	2	582	10,895	291	2.5%	116%

*ESTVs = equivalent simple treatment visits.

**Based on minimum performance standard of 250 patients per linear accelerator per year.

As indicated in the table above, the applicants project they will serve 291 patients on each of their two linear accelerators in the third year of operation following completion of the project, which exceeds the minimum performance standard of 250 patients required in 10A NCAC 14C .1903(a)(2).

In Section III.1(b), pages 50-53, the applicants describe their assumptions and methodology for projecting utilization of the LJCC linear accelerators. With regard to the historical utilization of the LJCC linear accelerators, the applicants state,

“During FY2012-FY2015, the number of unduplicated patients served on LJCC’s linear accelerators increased by a compound annual growth rate of approximately 1.7 percent. Although the number of patients increased in FY2015, the number of treatments slightly decreased. This is because the patients received fewer treatments

(procedures) than in the past years. ... Thus, the demand for LJCC's radiation therapy services continues to increase based on total patients served as opposed to total procedures performed. Demand is expected to continue to increase based on the projected population growth, aging and the related impact these factors will have on future cancer incidence rates for local residents."

On pages 51-52, the applicants describe their assumptions with regard to future utilization as follows:

"LJCC anticipates the replacement linear accelerator will be operational October 1, 2016. Thus, the initial three year full project years are defined as FY2017 through FY 2019. During the current project year (FY2016), LJCC conservatively projects linear accelerator procedures to remain consistent with FY2015 utilization. To project utilization during the initial three year project years, LJCC utilized two-thirds of the projected growth rate for Pitt County population age 65 and older ($3.7\% \times 2/3 = 2.5\%$). LJCC applied this growth rate to the number of unduplicated linear accelerator patients and conservatively assumes a ratio of patients: procedures and patients; ESTVs will remain unchanged. ... LJCC utilized a projected growth rate that is based on a fraction of the projected growth rate for Pitt County population age 65 and older. The projected growth rate is also lower compared to the weighted average projected growth rate for service area residents age 65 and older (2.8%).

As described previously, radiation therapy utilization at LJCC is dramatically impacted by the limitations of the existing linear accelerators. The proposed replacement linear accelerator is expected to provide [sic] restore productivity via reduced downtime associated with [sic] obsolete and unreliable Siemens Oncor machine.

Additionally, LJCC has referred numerous Pitt County patients to the Marion L. Shepard Cancer Center when a significantly superior treatment plan was achieved on a new state-of-the-art linear accelerator. Thus, this portion of patient utilization is expected to be recaptured once the replacement linear accelerator is operational at LJCC."

As shown above, the applicants' utilization projections are based on the historical utilization of LJCC's existing linear accelerators from FY2012 to FY2015. Also, the applicants' projected utilization is supported by the projected growth and aging of the service area population. Exhibit 20 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 applicants adequately demonstrated the need to acquire a replacement linear accelerator.

Access

In Section VI.2, page 77, the applicants state their commitment to provide services to all patients who need the services regardless of their ability to pay, racial/ethnic origin, age, gender, physical or mental conditions or other conditions that would classify them as

underserved. In Section VI.15, page 92, the applicants project that 72 percent of patients to be served will be Medicare or Medicaid recipients. The applicants adequately demonstrate the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicants adequately identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated 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.

NA

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

CA

In Section III.3, pages 57-59, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicants state that maintaining the status quo is not an effective alternative because the existing linear accelerator equipment has exceeded its depreciable useful life and lacks the capabilities to meet the current standard of care.
- Replace and Update Components of the Existing Equipment – The applicants state that Siemens is no longer manufacturing linear accelerators and will soon discontinue their service department as well, so this alternative was rejected.

After considering those alternatives, the applicants state the alternative represented in the application is the most effective alternative to meet the identified need.

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

In summary, the applicants adequately demonstrate 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 and NewCo Cancer Services, LLC d/b/a Leo Jenkins Cancer Center shall materially comply with all representations made in the certificate of need application.**
 2. **Vidant Radiation Oncology, LLC and NewCo Cancer Services, LLC d/b/a Leo Jenkins Cancer Center shall acquire no more than one linear accelerator to replace the existing linear accelerator for a total of no more than two linear accelerators upon project completion. The applicants shall dispose of the existing linear accelerator by removing it from North Carolina.**
 3. **Vidant Radiation Oncology, LLC and NewCo Cancer Services, LLC d/b/a Leo Jenkins Cancer Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
 4. **Vidant Radiation Oncology, LLC and NewCo Cancer Services, LLC d/b/a Leo Jenkins Cancer Center 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 Section VIII.1, page 105, the applicants state the total capital cost is projected to be as follows:

LJCC Linear Accelerator Project Capital Cost

Construction/Renovation Costs	\$225,750
Equipment/Miscellaneous	\$3,345,896
TOTAL CAPITAL COST	\$3,571,646

Source: Tables on pages 104-105 of the application.

In Section IX.1, page 113, the applicants state there will be no start-up expenses and no initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 108, the applicants state that \$322,270 of the project capital costs will be funded by the accumulated reserves of VRO and \$3,249,376 will be funded by an equipment lease. In Exhibit 27, the applicants provide a letter dated November 12, 2015, from the Vice

President of VRO, documenting its intention to fund up to \$350,000 in capital costs for the proposed project. Also, Exhibit 11 contains a copy of an equipment lease for a Varian linear accelerator between VRO and GE Capital. Exhibit 11 also contains a copy of the Consolidated Financial Statements for Vidant Health that indicate it had \$136 million in cash and cash equivalents as of September 30, 2014. The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for LJCC’s linear accelerator services (Form C), the applicants project that revenues will exceed operating expenses in the third operating year of the project, as shown in the table below.

LJCC Linear Accelerator Services

	FY2017	FY2018	FY2019
Total Net Revenues	\$5,984,821	\$6,438,665	\$6,926,925
Total Operating Expenses	\$6,354,036	\$6,535,036	\$6,726,043
Net Income (Loss)	(\$369,214)	(\$96,371)	\$200,882

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project. Furthermore, the applicants adequately demonstrate 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 applicants, VRO and LJCC, propose to acquire a linear accelerator to replace one of the two existing linear accelerators at the Leo Jenkins Cancer Center located at 600 Moye Boulevard in Greenville.

On page 125, the 2015 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 2015 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 2016 SMFP.

	Linear Accelerators	Total ESTV Procedures	Average ESTV Per Linear Accelerator
Vidant Beaufort Hospital	1	1,881	1,881
Vidant Roanoke-Chowan Hospital	1	2,596	2,596
Leo Jenkins Cancer Center	2	10,772	5,386
NC Radiation Therapy - Greenville	2	10,916	5,458
Vidant Medical Center	1	2,053	2,053

Source: 2016 SMFP, Table 9G, page 138.

The applicants proposes to acquire one linear accelerator to replace an existing linear accelerator located at LJCC. Therefore, the applicants do not propose to increase the inventory of linear accelerators in the service area and no new services will be offered. The applicants state the existing linear accelerator equipment has reached the end of its useful life and has become increasingly unreliable, and that it does not have the capabilities necessary to meet the current standard of care. The applicants adequately demonstrated the need to replace the existing linear accelerator. The applicants adequately demonstrate 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 applicants adequately demonstrate 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 VII.1, page 94, the applicants state that they currently employ 16.35 full-time equivalent (FTE) to staff the linear accelerator services at LJCC, and that they do not project any changes to staffing associated with the proposed project. Exhibit 3 contains a copy of a letter from the Medical Director for Radiation Oncology at LJCC, expressing their support for the proposed project. Exhibit 20 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 II.2, pages 22-23, the applicants describe the manner in which they will provide the necessary ancillary and support services. Exhibit 20 contains letters of support from physicians. The applicants adequately demonstrate that necessary ancillary and support services are 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.

NA

- (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

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. More current data, particularly with regard to the estimated uninsured percentages, was not available.

County	Total # of Medicaid Eligibles as % of Total Population June 2010	Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010	% Uninsured CY2008-2009 (Estimate by Cecil G. Sheps Center)
Pitt	16%	6.7%	21.3%
Statewide	17%	6.7%	19.7%

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the linear accelerator services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicants' current payer 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.

In Section VI.13, page 88, the applicants report the following payer mix for LJCC’s linear accelerator services for FY2015:

Payer Category	Linear Accelerator Services as Percent of Total
Self Pay	0.2%
Medicare	55.1%
Medicaid	16.6%
Blue Cross	15.2%
Commercial	7.1%
Other (TriCare, SEHP, other government)	5.8%
Total	100.0%

The applicants demonstrate that medically underserved populations currently have adequate access to the applicants’ existing services and is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 86, the applicants state, “LJCC is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, as previously stated, LJCC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.” In Section VI.10, page 84, the applicants state that no civil rights access complaints have been filed against LJCC or VRO in 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 VI.15, page 92, the applicants project the following payer mix for LJCC’s linear accelerator services during the second operating year (FY2018):

Payer Category	Linear Accelerator Services as Percent of Total
Self Pay	0.2%
Medicare	55.1%
Medicaid	16.6%
Blue Cross	15.2%
Commercial	7.1%
Other (TriCare, SEHP, other government)	5.8%
Total	100.0%

On page 93, the applicants state, “LJCC expects the payor mix for radiation oncology services in the near future to be comparable to the current LJCC payor mix.” The applicants demonstrated 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 VI.9, page 83, the applicants describe the range of means by which a person will have access to LJCC’s linear accelerator services. The applicants adequately demonstrate 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 V.1, page 70, the applicants state 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, LJCC already has extensive relationships with health professional training programs. On page 70, the applicants provide a list of educational institutions with which LJCC and VMC training arrangements, including Brody School of Medicine at ECU, and the ECU Schools of Nursing, Allied Health Sciences, and Social Work, among other. 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

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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 2016 SMFP.

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Leo Jenkins Cancer Center	2	10,772	5,386
NC Radiation Therapy - Greenville	2	10,916	5,458
Vidant Medical Center	1	2,053	2,053

Source: 2016 SMFP, Table 9G, page 138.

The applicants propose to acquire one linear accelerator to replace an existing linear accelerator located at LJCC. In Section V.7, pages 74-75, the applicants discuss how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicants state,

“The proposed replacement linear accelerator represents the current standard of care for local patients. More specifically, the proposed TrueBeam platform linear accelerator from Varian Medical Systems significantly upgrades the clinical treatment capabilities available to patients treated at LJCC and helps achieve the goals of increased accuracy,

increased throughput, enhanced patient safety, and improved patient experience, and greater physician and patient satisfaction....

As described in Section III.3, LJCC has selected a cost effective alternative for the proposed replacement linear accelerator. The proposed project is indicative of LJCC's commitment to containing healthcare costs. ... Because of the existing equipment's instability, maintenance becomes more costly each year, and the equipment cannot provide the level of care needed by a modern radiation therapy program. Moreover, the proposed replacement equipment can deliver higher doses of radiation much faster and with greater accuracy than the existing equipment. As such, the most effective, value-based alternative is to expend capital for significantly better equipment and avoid increasing operational costs for an outdated accelerator."

See also Sections II, III, V, VI and VII where the applicants discuss 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 applicants adequately demonstrate 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 applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is 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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In Section II.7, pages 27-29, the applicants describe the methods used by LJCC to insure and maintain quality care. In Section II.7(c), page 29, the applicants state that none of the licensed health service facilities owned or operated by the applicants, as identified by the applicants in Section I.12, pages 10-12, 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