

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: August 28, 2015

Findings Date: August 28, 2015

Project Analyst: Jane Rhoe-Jones

Team Leader: Lisa Pittman

Assistant Chief: Martha J. Frisone

Project ID #: J-11035-15

Facility: UNC Hospitals Radiology Oncology, Hillsborough Campus

FID #: 090274

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Relocate one existing linear accelerator from the main campus to the Hillsborough campus (Change in scope for Project ID# J-8330-09)

### 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

University of North Carolina Hospitals at Chapel Hill [UNC Hospitals] proposes to move one existing linear accelerator from the main campus in Chapel Hill to its satellite campus in Hillsborough (both campuses are in Orange County).

#### **Need Determination**

UNC-CH does not propose to acquire any medical equipment or develop any health service facility beds or services for which there is a need determination in the 2015 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations that are applicable to the proposal.

## Policies

Policy *GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES* on page 39 of the 2015 State Medical Facilities Plan (SMFP) is applicable to this review. 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. 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 54-55, the applicant states that its lighting systems, water systems, heating, ventilation and air-conditioning (HVAC) systems will provide higher energy efficiency in accordance with energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The applicant also states that minor equipment such as ice machines will be evaluated prior to purchase, and as well will meet required state standards. The applicant further states that the above named systems and minor equipment will not adversely affect patient or resident health, safety or infection control. In addition, the applicant states that it will research and evaluate other energy conservation measures. Per the applicant,

*“As detailed above, the design of the proposed project will incorporate materials and equipment which enhance the containment of utilities and energy costs.”*

## **Conclusion**

In summary, there is no need determination applicable to this proposed project. The applicant adequately demonstrates that the application is consistent with Policy GEN-4 in the January 2015 SMFP. Therefore, 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.

NC

The applicant proposes to relocate an existing linear accelerator which is currently located on the main hospital campus in Chapel Hill to its satellite site in Hillsborough. In Section II.1, pages 29-32, the applicant describes the project, quoted as follows:

*“In order to ensure that adequate radiation therapy services are available for the residents of Orange County and surrounding communities, UNC Hospitals proposes to relocate an existing linear accelerator from its main campus to its Hillsborough campus and develop radiology oncology services in Hillsborough. UNC Hospitals proposes to relocate its existing Siemens Artiste linear accelerator to a medical office building co-located with the medical oncology services located on the Hillsborough campus. As UNC Hospitals Hillsborough Campus is not yet operational, the proposed project is a change in scope to the original application for that facility (Project ID# J-8330-09).*

...

*... The following cancer services are currently and will continue to be offered in Hillsborough:*

- *Medical oncology*
- *Surgical oncology*
- *Infusions*
- *Injections*
- *All routine labs*
- *Ultrasound*
- *Bone density*
- *Mammography, including screening, diagnostic, breast ultrasound, and ultrasound procedures*

*... The proposed project will expand geographic access to Hillsborough residents and surrounding communities that currently lack convenient local access to radiation oncology services. ... will allow for enhanced coordination of care.*

*The proposed relocation of a linear accelerator will require the construction of 3,000 square feet additional space to house a vault and support space. The space will be constructed adjacent to the existing medical oncology clinic on the Hillsborough campus ... In addition to the vault for the linear accelerator, the proposed project includes two waiting areas, a control area, a workroom, a restroom, and two changing rooms all related to the provision of radiation therapy services, as shown in the proposed line drawings in Exhibit 5.”*

### **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.” Orange County is located in Service Area 14 which also includes Chatham County.

In III.5(a), page 62, the applicant states:

*“The 2015 SMFP identifies UNC Hospitals as part of the Orange County linear accelerator service area, as used in the development of the linear accelerator need determination. The remainder of UNC Hospitals’ service area includes every other county in North Carolina and a small percentage of patients from other states. During most fiscal years, UNC Hospitals treats radiation oncology patients from more than half of North Carolina’s 100 counties.”*

In Section III.4(b), pages 60-62 and Section III.5(c), pages 63-64, the applicant provides current and projected patient origin for linear accelerator services during the first two years of operation (FY2017-FY2018). The following table illustrates projected utilization on the Hillsborough campus.

<b>Hillsborough Linear Accelerator Services Projected Patient Origin - PY2017 and PY2018</b>		
<b>County of Origin</b>	<b>PY2017 Percent of Total Treatments</b>	<b>PY2018 Percent of Total Treatments</b>
Orange	17.8%	17.8%
Wake	15.7%	15.7%
Chatham*	9.1%	9.1%
Alamance*	8.8%	8.8%
Durham*	7.4%	7.4%
Lee	7.1%	7.1%
Cumberland	4.6%	4.6%
Harnett	3.6%	3.6%
Guilford	2.1%	2.1%
Robeson	1.6%	1.6%
Wayne	1.6%	1.6%
Johnston	1.5%	1.5%
Person*	1.3%	1.3%
Nash	1.2%	1.2%
Halifax	1.1%	1.1%
Randolph	1.1%	1.1%
Sampson	1.0%	1.0%
Caswell*	0.3%	0.3%
Other NC Counties	11.4%	11.4%
Other States	1.7%	1.7%
<b>TOTAL</b>	<b>100.0%</b>	<b>100.0%</b>

\*Contiguous counties.

In Section III.1(b), pages 48-52, the applicant describes its assumptions regarding the patient origin projections. In Section, III.5(d), page 65, the applicant states that it does not expect any impact on patient origin with the proposed relocation of a linear accelerator to the Hillsborough campus. In response to comments, the applicant states “*it will ... provide all UNC Health Care System patients with an additional site.*” (Emphasis added.) As shown above, UNC Hospitals serves linear accelerator patients from all over the state. In the absence of any historical patient origin data for linear accelerator services provided on the Hillsborough campus, it is reasonable to assume patient origin on the Hillsborough campus (licensed as part of UNC Hospitals) would be the same or similar to the historic patient origin on the Chapel Hill campus, located in the same county.

The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section III.1(a) and (b) of the application, pages 40-51, the applicant describes the factors which it states support the need to relocate an existing linear accelerator from Chapel Hill to Hillsborough, including:

- Expansion of geographic access for cancer patients particularly those residing in central and northern Orange County and the current concentration of linear accelerator capacity in southern Orange County (pages 40-41).
- Need for relocated linear accelerator services given the development of healthcare services in Hillsborough, including oncology services (pages 41-43).
- The projected population growth and aging population in the proposed service area (pages 43-47).

Below, each factor is briefly described:

#### Expansion of Geographic Access

*“... Cancer care was once considered a specialty, tertiary service available only at tertiary and academic medical centers. However, as the incidence of disease continues to grow and treatment options become more widely available, more community hospitals are able to offer a wider range of services. ...*

*This growth in providers has resulted in an increase in geographic access for patients and is a result of an understanding of the best practices in cancer care. ... The development of the proposed Hillsborough facility will reduce patient travel time and promote more time for patients to heal.”*

#### Need for Relocated Linear Accelerator Services

*“..., the provision of radiation oncology services in Orange County are currently limited to the Southern portion of the county. ... With the ongoing development of extensive healthcare services in Hillsborough, including medical oncology services, and the high referral patterns for radiation services from medical oncologists, the proposed UNC radiation oncology facility will provide patients with convenient, accessible care in a more proximate location.”*

#### Overall Population Growth in Orange County

*“According to data from the North Carolina Office of State Budget and Management (NC OSBM), Exhibit 14, Orange County is the fifteenth fastest growing county in North Carolina based on numerical growth and the fifteenth fastest county based on percentage growth. ... NC OSBM projects the population of Orange County to grow 13.2 percent between 2010 and 2020. Within this decade, Orange County is projected to add over 17,000 people.”*

#### Aging Population

*“By 2020, nearly 15 percent of the total population in Orange County will be over the age of 65 ..., up from approximately 10 percent in 2010 as shown in Exhibit 16.*

*Further, between 2010 and 2020, Orange County’s population over the age of 65 is projected to grow by 72.1 percent.*

*These data are significant because, as the population ages, the incidence of cancer rises. Moreover, data from a study published in the Journal of Clinical Oncology approximates that the number of adults 65 and older needing radiation therapy will increase by 38 percent between 2010 and 2020.*

*UNC Hospitals believes there is a correlation between population growth and aging and the demand for radiation therapy services based on national studies as well as Orange County provider data that provide evidence for this correlation.*

*UNC Hospitals, the sole provider of radiation therapy services in Orange County, examined its historical utilization data. According to the SMFP, radiation therapy utilization (as measured by Equivalent Simple Treatment Visits or ESTVs) increased at a 6.3 percent compound annual growth rate (CAGR) from 2009 to 2013, as shown below. ... Over the same time period, the North Carolina Office of State Budget and Management (NC OSBM) estimated that the total population of Orange County grew at a 1.4 percent CAGR.”*

The applicant is the only provider of radiation therapy services located in the Orange-Chatham County linear accelerator planning area (Area 14). On page 46, the applicant illustrates that growth in Orange County population has resulted in higher demand for radiation therapy services. As shown in the table below, radiation therapy treatments increased 6.3% while the population only increased 1.4% over a four year period.

<b>UNC Hospitals</b>						
<b>FFY</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>	<b>2013</b>	<b>CAGR</b>
<b>Total ESTVs – Orange County Providers</b>	25,953	30,238	30,387	27,450	33,099	6.3%
<b>Orange County Population</b>	132,215	134,303	135,080	138,366	139,694	1.4%

From page 46 of application.

In Section III.1(b), page 49, the applicant provides a table showing the projected utilization for the proposed Hillsborough linear accelerator in the first three fiscal years of operation following completion of the project, which is summarized in the following table. In Section III.1(b), pages 48-52, the applicant describes its assumptions for projecting utilization of the proposed Hillsborough linear accelerator. In Section IV.1(d), page 70, the applicant states that the utilization data is “based on the pro formas, recent financial statements, and discussions with departmental administration.”

<b>UNCH Hillsborough Campus                      Projected Linear Accelerator Utilization                      FY2017-FY2020</b>			
<b>Year</b>	<b># of Units</b>	<b>ESTV* Procedures</b>	<b>Percent Increase ESTVs</b>
FY 2017 (interim)	1	1,748	---
FY2018**	1	3,800	8.7%
FY2019	1	4,180	10.0%
FY2020	1	4,598	10.0%
*ESTVs = equivalent simple treatment visits. **8.7% annual increase was calculated based on the 6 month data for FY2017 annualized (1,748 x 2 = 3,496; 3,800 - 3,496 = 304; 304/3496 = 8.7%)			

As indicated in the table above, the applicant projects it will perform 4,598 ESTVs on its proposed Hillsborough linear accelerator following completion of the project. The applicant assumes an increase in ESTVs of 8.7 – 10.0% annually. However, the applicant does not provide any explanation in the application to document or support the reasonableness of its assumptions. Moreover, the applicant does not provide any explanation in the application regarding how it determined the number of ESTVs (as opposed to the number of patients or treatments). Thus, there is insufficient information to determine if the number of ESTVs is reasonable. Furthermore, Form C of the pro formas shows a “Volume Growth Factor” which ranges from 3.4% per year to 15.5% per year. However, the applicant does not provide any explanation in the application regarding these “volume growth factors,” which differ from the ones shown in the table above. Therefore, the applicant does not adequately demonstrate that projected volumes for the proposed service are based on reasonable and adequately supported assumptions. Consequently, the applicant does not adequately demonstrate the need to relocate a linear accelerator to the Hillsborough campus.

**Access**

In Section VI.2, page 86, the applicant states residents of the service area will have access to the proposed services, including those residents who are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups. In Section VI.14, page 96, the applicant projects that 12.2% of treatments will be provided to Medicaid recipients and 41.5% will be provided to Medicare beneficiaries.

The applicant adequately demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

In summary, the applicant adequately identifies the population to be served and adequately demonstrates the extent to which all residents of the area, including medically underserved groups, are likely to have access to the proposed services. However, the applicant does not adequately demonstrate projected utilization is based on reasonable and adequately supported



assumptions. Therefore the applicant does not adequately demonstrate the need the population projected to be served has for the proposed project. Therefore, the application is not 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 III.1, page 41, the applicant states:

*“Service Area 14 has one provider of radiation oncology services, UNC Hospitals, which currently offers its services only in Chapel Hill. The Chapel Hill campus is currently home to five linear accelerators, as noted in Section II.12(d). Additionally, please note that UNC Hospitals will be operationalizing one additional linear accelerator under Policy AC-3 (Project ID # J-8611-10) that will begin providing services in mid-2015. This unit will be placed at UNC Hospitals’ main campus in Chapel Hill and will serve to enhance its multiple educational programs as well as clinical services. As a result, all existing and previously approved radiation oncology services are currently limited to southern Orange County. The proposed project will expand geographic access to residents of central and northern Orange County and as such to the county as a whole. Further, given the development of the AC-3 linear accelerator in mid-2015, the proposed relocation will not result in the reduction of capacity on the main campus but rather will provide patients with a more proximate location from which to receive treatments.”*

This proposed project is projected to be operational January 1, 2017 and the one approved additional linear accelerator under Policy AC-3 (Project ID # J-8611-10) is projected to become operational in mid-2015. Thus the applicant states that services will be offered at the current level at the main campus while services are expanded at the Hillsborough campus. The applicant demonstrates that the needs of the population presently served will be adequately met by the proposed relocation of the equipment and that there will be no 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. 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.

In Section III.3, pages 55-56, the applicant states the following alternatives were considered:

- Maintain the Status Quo - The applicant states that this is not the most effective alternative because it does not offer patients a more proximate location for radiation oncology services; thereby reducing the burden of traveling, since fatigue is a common side effect of radiation therapy services.
- Relocate to Another Site in Orange County - The applicant states that this would not allow the immediate co-location of radiology oncology services with medical oncology and other cancer care and hospital services. Given the existing services in Hillsborough, another site is not feasible.
- Relocate Existing Linear Accelerator to Hillsborough - The applicant states this is the most effective alternative: to co-locate a linear accelerator with the existing medical oncology clinic on the Hillsborough campus.

However, the applicant does not adequately demonstrate that the proposal is its least costly or most effective alternative because the applicant does not adequately demonstrate an unmet need for the proposed project. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

Furthermore, the application is not conforming to all other statutory review criteria, and thus, is not approvable. See Criteria (3), (5), (6) and (18a). A project that cannot be approved cannot be an effective alternative.

Therefore, the application is not conforming to this criterion and is denied.

- (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.

NC

In Section VIII.1(c), pages 106-107, the applicant states that the total capital cost of the project will be \$2,839,864, including \$62,707 for site costs, \$2,555,980 for construction costs, and \$221,177 for miscellaneous project costs (including \$70,000 for equipment relocation, \$36,177 for landscaping, and \$115,000 for architect/engineering fees). In Section IX, page 112, the applicant projects there will be no start-up expenses or initial operating expenses associated with the proposed project. The Hillsborough campus was approved in 2009. Phase I of that project is expected to be operational in September 2015, well before completion of this project. In Section VIII.3, page 108, the applicant states that the project will be funded by UNC Hospitals' accumulated reserves. Exhibit 25 contains an April 8, 2015 letter signed by the Executive Vice President and Chief Financial Officer for UNC Hospitals, which states:

“... The total capital expenditure for this project is estimated to be \$2,839,864. ...  
UNC Hospitals will fund the capital cost from existing accumulated cash reserves.  
...”

Exhibit 26 of the application contains the audited financial statements for UNC Hospitals for the years ending June 30, 2013 and June 30, 2014. As of June 30, 2014, UNC Hospitals had \$43,554,656 in cash and cash equivalents and \$1,251,347,049 in total net assets (total assets less total liabilities). The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

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

<b>UNC Hospitals - Radiation Oncology Services</b>			
	<b>FY2018 Year 1</b>	<b>FY2019 Year 2</b>	<b>FY2020 Year 3</b>
Total Revenue	\$43,287,507	\$48,459,160	\$52,505,396
Total Expenses	\$24,999,762	\$25,663,823	\$23,319,019
Net Income (Loss)	\$18,287,745	\$22,795,337	\$26,186,377

Source: Applicant's Form C on pages 128-129 of the application.

However, the applicant did not adequately demonstrate that projected operating costs and revenues are based on reasonable assumptions regarding projected utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, since projected operating costs and revenues are based in part on projected utilization, they are also questionable.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital of the project. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues. Therefore, the application is not 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.

NC

UNC Hospitals in Chapel Hill is the only hospital located in Orange County. UNC Hospitals currently provides radiation and medical oncology services to the residents of Orange and surrounding counties, as well as 50% of the counties in the state. It is the only provider of these services located in Orange County. The applicant proposes to relocate one of its five existing linear accelerators to its Hillsborough Campus, located at 460 Waterstone Drive

(Orange County). UNC Hospitals currently operates a medical office building on this site and UNC Hospitals is in the process of developing 68 acute care beds on the Hillsborough Campus (Project ID# J-8330-09). The 2015 SMFP defines Linear Accelerator Service Area 14 as Orange and Chatham counties. The applicant does not propose to increase the number of linear accelerators in Linear Accelerator Service Area 14. However, the applicant does not adequately demonstrate the need to relocate an existing linear accelerator to the Hillsborough campus because the applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the applicant does not adequately demonstrate that the proposed project will not result in unnecessary duplication of existing or approved linear accelerators. Consequently, the application is not 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, pages 97-98, the applicant provides the current (FY2014) and proposed Year 2 (FY2018) staffing for its radiation oncology services, as shown below in the table.

<b>UNC Hospitals - Radiation Oncology Staffing</b>		
<b>Position</b>	<b>Current Staffing</b>	<b>Proposed Staffing Year 2</b>
Administrative Support	11.30	12.7
Clinical Support	1.11	3.04
Dosimetrist	6.93	8.10
Nurse	7.46	9.51
Tech	17.32	20.01
Tech Supervisor	1.00	1.00
Physicist	4.23	4.50
Manager	0.48	1.00
<b>TOTAL</b>	<b>49.83</b>	<b>59.86</b>

As shown in the table above, the applicant proposes to add 10.03 full-time equivalent (FTE) positions as part of the proposed project. In Section VII.3, page 99, and Section VII.6, pages 100-101, the applicant describes its recruitment and retention procedures, and indicates that it does not anticipate any difficulties identifying, hiring, and retaining qualified staff for the proposed project. In Section VII.8, page 102, the applicant identifies Lawrence B. Marks, M.D. as the Medical Director for the proposed project. Exhibit 18 contains a copy of a letter from Dr. Marks expressing his support for the project and willingness to serve as medical director. Exhibit 32 of the application contains copies of letters from physicians and surgeons 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 33-34, and Exhibit 6, the applicant documents that all of the necessary ancillary and support services for the proposed services that are not available on-site will be provided by referral to UNC Hospitals' main campus. In Section V.2, page 75, the applicant states that since UNC Hospitals is an academic medical center teaching hospital, no transfer agreements are required for UNC Hospitals' patients. The applicant further states that standard transfer agreements exist between UNC Hospitals and a variety of hospitals and nursing facilities in the state. Pages 76-77 contain a chart listing UNC Hospitals' existing transfer agreements; while Exhibit 20 contains a copy of a typical hospital transfer agreement. Moreover, the Hillsborough campus is licensed as part of UNC Hospitals. Exhibit 32 contains copies of letters from physicians and surgeons expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the proposed project will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

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

NA

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

NA

- (11) Repealed effective July 1, 1987.

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

C

In Section XI, pages 117-119, the applicant discusses relocating the Siemens Artiste linear accelerator to its Hillsborough Campus which is under construction. The linear accelerator will be housed in 3,000 square feet of new construction to be added to the existing medical office building on the campus. Exhibit 30 of the application contains a copy of a letter from an architect which estimates the construction costs for the proposed linear accelerator will be \$2,839,864, which is consistent with the capital cost projections provided by the applicant in Section VIII.1, pages 106-107. In Section XI.7, pages 122-123, the applicant describes the methods that will be used by the facility to maintain energy efficient 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 for the project as proposed, 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 VI.13, page 94, the applicant reports the payor mix for linear accelerator services at UNC Hospitals for FY2014, which is summarized in the following table:

<b>Linear Accelerator Services at UNCH-CH Payor Category</b>	<b>FY2014 Treatments as % of Total</b>
Self-Pay/Indigent/Charity	7.2%
Medicare/Medicare Managed Care	41.5%
Medicaid	12.2%
Commercial Insurance/Managed Care	0.5%
Managed Care	32.0%
Other Government	6.6%
<b>Total</b>	<b>100.0%</b>

As illustrated in the table above, 53.7% of all inpatient linear accelerator treatments were paid for by Medicare or Medicaid.

The Division of Medical Assistance (DMA) maintains a website which provides the number of persons eligible for Medicaid in North Carolina, and estimates the percentage of uninsured people for each county. The following table illustrates those percentages for Orange and Chatham counties and statewide.

	<b>Total # of Medicaid Eligibles as % of Total Population June 2010</b>	<b>Total # of Medicaid Eligibles Age 21 and older as % of Total Population June 2010</b>	<b>% Uninsured CY 2008-2009 (Estimate by Cecil G. Sheps Center)</b>
Orange County	8.6%	3.5%	18.9%
Chatham County	11.6%	4.1%	19.3%
Statewide	16.5%	6.7%	19.7%

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

The majority of Medicaid eligibles are children under the age of 21. This age group does not typically utilize the same health services at the same rate as older segments of the population.

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

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina.

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

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's 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 93 the applicant states:

*“UNC Hospitals has long since satisfied its ‘free care’ obligation under the Hill-Burton Act. Charity care provided by UNC Hospitals for Fiscal Year 2014 is estimated to be \$191 million (15.64 percent of Net Revenue). UNC Hospitals provides care to all persons based only on their need for care, and without regard to minority status or handicap/disability.”*

In Section VI.10 (a), page 93, the applicant states that no Office of Civil Rights complaints have been filed against it 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

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In Section VI.14, page 96, the applicant provides the projected payor mix for the second full fiscal year of operation (FY2019) for UNC Hospitals' linear accelerator services, as shown below in the table.



UNC Hospitals' Linear Accelerator Services Payor Category	FY 7/1/18-6/30/19 Treatments as % of Total
Self-Pay/Indigent/Charity	7.2%
Medicare/Medicare Managed Care	41.5%
Medicaid	12.2%
Commercial Insurance/Managed Care	0.5%
Managed Care	32.0%
Other Government	6.6%
<b>Total</b>	<b>100.0%</b>

On page 96, the applicant states, “*UNC Hospitals assumes its payor mix for radiation oncology will not change from its historical mix as shown in Section VI.12 [sic].*” The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

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

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In Section VI.9, page 140, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

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

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In Section V.1, pages 72-74, the applicant states since UNC Hospitals is an academic medical center teaching hospital, it serves as a teaching site for a broad range of healthcare disciplines, and that the relocated linear accelerator will be available as a clinical training site for area health professional training programs. The information provided in Section V.1 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.

NC

UNC Hospitals in Chapel Hill is the only hospital located in Orange County. UNC Hospitals currently provides radiation and medical oncology services to the residents of Orange and surrounding counties, as well as 50% of the counties in the state. It is the only provider of these services located in Orange County. The applicant proposes to relocate one of its five existing linear accelerators to its Hillsborough Campus, located at 460 Waterstone Drive (Orange County). UNC Hospitals currently operates a medical office building on this site and is in the process of developing 68 acute care beds on the Hillsborough Campus (Project ID# J-8330-09). The linear accelerator will be located in a 3,000 square foot addition to the existing medical office building. The 2015 SMFP defines Linear Accelerator Service Area 14 as Orange and Chatham counties. The applicant does not propose to increase the number of linear accelerators in Linear Accelerator Service Area 14.

In Section V.7, pages 82-84, the applicant discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. The applicant states,

*“... UNC Hospitals maintains that the development of radiation oncology services in Hillsborough will promote cost-effectiveness, quality and access to services in the proposed service area ...*

*UNC Hospitals, as a member of the larger UNC Health Care System, benefits from the significant cost saving measures through the consolidation of multiple services and large economies of scale. This efficiency results in lower costs that are passed to patients in the form of lower charges. Patients also benefit from the proposed project in terms of reduced out-of-pocket expenses related to traveling, such as gas and parking fees on the larger hospital campus. ...*

*UNC Hospitals also believes that the proposed project will promote the provision of quality healthcare services to patients in the service area. ... The location of the proposed hospital-based outpatient linear accelerator alongside an existing medical oncology clinic will allow for enhanced coordination of care. Medical oncologists are a top source of referrals for radiation oncology programs; therefore, the proposed location will benefit patients who may need radiation oncology treatments by providing them with the opportunity to continue to receive care at a location where they are already accustomed to receiving care.*

*Moreover, while this project is not specifically being developed to foster competition, the relocation of the existing linear accelerator will serve to improve access to services. ...”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

However, the applicant did not adequately demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. The applicant did not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. Moreover, the applicant did not adequately demonstrate 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 application is not 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 I.12(c), page 16, the applicant states that it currently owns, leases, or manages seven hospitals in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, no incidents occurred within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by UNC Hospitals in North Carolina. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all seven facilities, the applicant provides sufficient evidence that quality care has been provided in the past and adequately demonstrates that there is no pattern of substandard quality of care. Therefore, the application is conforming to this criterion.

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

NA