

**ATTACHMENT – REQUIRED STATE AGENCY FINDINGS**

**FINDINGS**

C = Conforming

CA – Conditional

NC – Nonconforming

NA = Not Applicable

Decision Date: November 21, 2016

Findings Date: November 21, 2016

Project Analyst: Julie Halatek

Team Leader: Lisa Pittman

Project ID #: J-11218-16

Facility: University of North Carolina Hospitals

FID #: 923517

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Acquire an additional CT simulator

**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

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

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

NA

The applicant, University of North Carolina Hospitals at Chapel Hill (UNC Hospitals), proposes to acquire an additional CT simulator to be located in the Department of Radiation Oncology on the main campus of the University of North Carolina Hospitals in Chapel Hill (Main Campus). The total cost for the proposed project is \$810,806.

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2016 State Medical Facilities Plan (SMFP). In addition, no policies in the 2016 SMFP are applicable to this review. Therefore, this criterion is not applicable in this review.

- (2) Repealed effective July 1, 1987.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

UNC Hospitals proposes to acquire an additional CT simulator for use in the Department of Radiation Oncology. In Section II.1(a), pages 29-33, the applicant states that it has two CT simulators on its hospital license, but only one of them is capable of use with patients about to receive radiation therapy from one of UNC Hospitals seven existing or approved linear accelerators. UNC Hospitals proposes to locate the CT simulator, which it states is the newest model of the same type of CT simulator it currently uses – in existing space. The applicant states that the existing space was developed specifically for use with a CT simulator as part of Project I.D. #J-7181-04, but that a CT simulator was never acquired because at the time it was determined to be unnecessary. According to the applicant, the existing space has been used for storage and will require only minor renovations.

**Patient Origin**

The 2016 SMFP does not define the service area for CT simulators. The Criteria and Standards for Computed Tomography Equipment (10A NCAC 14C .2300) do not define a service area. In Section III.5, page 74, the applicant states that it is part of the Orange County linear accelerator service area and identifies the primary service area as Orange County with additional in-migration from other counties in both North Carolina and other states.

In Section III.4(b), pages 71-73, the applicant provides the historical patient origin for CT simulator services, as shown in the table below.

<b>UNC Hospitals CT Simulator Historical Patient Origin – FY 2016</b>	
<b>County</b>	<b>% of Patients</b>
Orange	15.7%
Wake	14.3%
Chatham	8.9%
Alamance	7.7%
Durham	6.0%
Lee	4.8%
Cumberland	4.7%
Other Counties/States*	37.9%
<b>Total</b>	<b>100.0%</b>

\*Other Counties listed include Guilford, Harnett, Nash, Robeson, Johnston, New Hanover, Moore, Randolph, Sampson, Caswell, Halifax, Onslow, Person, Richmond, Franklin, Brunswick, Columbus, Craven, Dare, Granville, Hoke, Pitt, Wayne, Wilson, Carteret, Duplin, Forsyth, Pender, Warren, Bladen, Davison, Rockingham, Vance, Jones, Pasquotank, Greene, Northampton, Rowan, Scotland, Buncombe, Catawba, Gaston, Lenoir, Mecklenburg, Montgomery, Watauga, Alexander, Beaufort, Bertie, Burke, Cherokee, Chowan, Davie, Edgecombe, Haywood, Henderson, Hertford, Iredell, Jackson, Lincoln, Perquimans, Wilkes, and Yancey counties. “Other States” are not identified individually.

In Section III.5(c), pages 74-77, the applicant provides the projected patient origin for CT simulator services during the first two operating years following project completion, as shown in the table below.

<b>UNC Hospitals CT Simulator Projected Patient Origin – FYs 2018-2019</b>				
<b>County</b>	<b>FY 2018</b>		<b>FY 2019</b>	
	<b># of Patients</b>	<b>% of Patients</b>	<b># of Patients</b>	<b>% of Patients</b>
Orange	236	15.7%	276	15.7%
Wake	216	14.3%	252	14.3%
Chatham	134	8.9%	157	8.9%
Alamance	116	7.7%	135	7.7%
Durham	90	6.0%	105	6.0%
Lee	73	4.8%	85	4.8%
Cumberland	70	4.7%	82	4.7%
Other Counties/States*	569	37.9%	663	37.9%
<b>Total</b>	<b>1,504</b>	<b>100.0%</b>	<b>1,755</b>	<b>100.0%</b>

\*Other Counties listed include Guilford, Harnett, Nash, Robeson, Johnston, New Hanover, Moore, Randolph, Sampson, Caswell, Halifax, Onslow, Person, Richmond, Franklin, Brunswick, Columbus, Craven, Dare, Granville, Hoke, Pitt, Wayne, Wilson, Carteret, Duplin, Forsyth, Pender, Warren, Bladen, Davison, Rockingham, Vance, Jones, Pasquotank, Greene, Northampton, Rowan, Scotland, Buncombe, Catawba, Gaston, Lenoir, Mecklenburg, Montgomery, Watauga, Alexander, Beaufort, Bertie, Burke, Cherokee, Chowan, Davie, Edgecombe, Haywood, Henderson, Hertford, Iredell, Jackson, Lincoln, Perquimans, Wilkes, and Yancey counties. “Other States” are not identified individually.

The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section III.1(a), pages 43-51, the applicant discusses the factors which it states support the need for the proposed project. On page 43, the applicant states that the overall need for the proposed project is based on the following factors:

- The need for additional simulation and treatment planning equipment (pages 43-47);
- The recent growth in radiation therapy utilization (page 47); and
- The projected population growth and aging in Orange County (pages 48-51).

The applicant demonstrates on the pages listed above the need for additional simulation and treatment planning equipment, the recent growth in utilization of radiation therapy, and the projected population growth in Orange County.

Additionally, the applicant notes on page 45 that page 132 of the 2016 SMFP states the following with regard to CT simulators in support of linear accelerators:

*“One simulator...can serve a facility with three linear accelerators or serve multiple facilities with up to four linear accelerators total.”*

On pages 45-46 of the application, the applicant states that the ratio of CT simulators to linear accelerators is lower at its campus than at any of the other sole service area providers in the state, as shown in the table below:

<b>Current Ratio of CT Simulators to Linear Accelerators – Sole Service Area Providers</b>					
<b>Facility</b>	<b>Service Area</b>	<b>County</b>	<b># of Simulators</b>	<b># of Linear Accelerators</b>	<b>Ratio of Simulators to Linear Accelerators</b>
Watauga Medical Center	3	Watauga	1	1	1.00
Lexington Medical Center	11	Davidson	1	1	1.00
Randolph Hospital	13	Randolph	1	1	1.00
Central Harnett Hospital*	21	Harnett	1	1	1.00
Onslow Radiation Therapy	25	Onslow	1	1	1.00
Alamance Regional Medical Center	15	Alamance	1	2	0.50
UNC Hospitals	14	Orange	1	6	0.17

\*Approved for one linear accelerator and one CT simulator as part of Project I.D. #M-11062-15.

The applicant states in Section III.1(b), page 63, that if the proposed CT simulator is approved, the ratio of CT simulators to linear accelerators will rise to 0.29, which is just higher than the suggested minimum standard in the 2016 SMFP.

*Projected Utilization*

In Section III.1(b), pages 52-63, the applicant provides the projected utilization of the CT simulator during the first three years following project completion as well as the assumptions and methodology used to project utilization. The applicant bases its utilization projection on the following assumptions:

- From FY 2014 to FY 2016, the number of treatments in the radiation oncology department has increased by a compound annual growth rate of 3.7 percent.
- Project I.D. #J-11035-15 (relocate one linear accelerator to the Hillsborough campus in Orange County) is projected to be operational on October 1, 2017.
- The Hillsborough campus will only serve outpatients, excluding CyberKnife patients.
- From FY 2016 to FY 2020, overall patient utilization in Orange County will increase at an average annual growth rate of 3.7 percent, which includes factors such as patients shifting from the Main Campus to the Hillsborough campus and different growth rates at each campus. (See page 60.)
- Project I.D. #J-10318-14 (develop a linear accelerator at a Holly Springs campus in Wake County) is projected to be operational on April 1, 2018.
- Utilization of the Holly Springs campus is based on patients shifting from the Main campus as well as from utilization projections that were included as part of Project I.D. #J-10318-14.
- The total projected patient treatments were converted to Equivalent Simple Treatment Visit (ESTV) procedures using UNC Hospitals' current ratio of 1.41 ESTVs per patient treatment. (See page 61.)
- The ratio of CT simulator patients to patient treatments at UNC Hospitals will be projected at the same ratio as FY 2016 (0.056 simulation patients per treatment). (See pages 62-63.)

On page 63, the applicant provides the historical and projected utilization of treatments and simulation patients, as shown in the table below.

<b>UNC Hospitals Radiation Oncology Historical and Projected Utilization</b>					
	<b>FY 2016</b>	<b>FY 2017</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Treatments	24,713	25,331	26,803	31,265	33,730
Ratio	0.056	0.056	0.056	0.056	0.056
Simulation Patients	1,387	1,422	1,504	1,755	1,893

Projected utilization is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire an additional CT simulator.

**Access**

In Section VI.2, pages 95-96, the applicant states that UNC Hospitals has the obligation to provide any North Carolina citizen medically necessary treatment and it does not deny services to persons in need of medical care based on race, sex, creed, age, handicap, financial status, or lack of medical insurance. In Section VI.15, page 105, the applicant projects that 39.6 percent of CT simulator patients to be served will be Medicare beneficiaries and 9.8 percent will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will likely 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 likely 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 66-68, the applicant discusses the alternatives it considered prior to submitting this application, which include:

- **Maintain the Status Quo:** the applicant states that maintaining the status quo would result in limited options for patients should the equipment malfunction or require maintenance, since there is currently only one CT simulator available. The applicant also states that with the expected growth in utilization of radiation therapy services as well as the population growth in Orange County, this option was not practical. Therefore, this alternative was rejected.
- **Acquire a CT Simulator at Another Location:** the applicant states that locating a CT simulator at one of its other radiation therapy services sites is not possible because the sites were not planned to include simulation and treatment planning services on-site. The applicant also states that if the CT simulator was located at another site, it could not provide backup for the existing CT simulator in the event of malfunction or maintenance. Therefore, this alternative was rejected.
- **Develop the Project as Proposed:** the applicant states that this is the most reasonable, cost-effective, and timely option for meeting the needs of the Department of Radiation Oncology, because the Main Campus houses most of the linear accelerators owned by the applicant and the need for the CT simulator is based on projected utilization of the Main Campus. The applicant also states that this alternative has existing space that will require only minor renovations as opposed to having to develop new space or heavily renovate existing space.

After considering those 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 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 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. University of North Carolina Hospitals at Chapel Hill shall materially comply with all representations made in the certificate of need application.**
  - 2. University of North Carolina Hospitals at Chapel Hill shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VIII of the application and that would otherwise require a certificate of need.**
  - 3. University of North Carolina Hospitals at Chapel Hill shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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

UNC Hospitals proposes to acquire an additional CT simulator for use in its Department of Radiation Oncology.

**Capital and Working Capital Costs**

In Section VIII.2, pages 115-116, the applicant states the total capital cost is projected to be \$810,806, which includes \$272,566 in construction costs, \$488,240 for the CT simulator, and \$100,000 for architect and consultant fees. In Section IX.1, page 121, the applicant states there will be no start-up expenses and no initial operating expenses associated with the project.

**Availability of Funds**

In Section VIII.3, page 116, the applicant states the capital cost of the project will be funded with accumulated reserves of UNC Hospitals. Exhibit 25 contains a letter dated August 15, 2016 from the Executive Vice President and Chief Financial Officer of UNC Hospitals, documenting the availability of sufficient funds for the capital cost of the proposed project. Exhibit 26 contains the audited financial statements of UNC Hospitals, which indicate that as

of June 30, 2015, UNC Hospitals had \$125,863,753 in cash and cash equivalents; \$608,825,428 in total current assets; and a total net position (total assets less total liabilities) of \$1,223,645,247. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

**Financial Feasibility**

In the pro forma financial statements (Forms C and D), the applicant provides financial information for UNC Hospitals’ Department of Radiation Oncology, as summarized below.

<b>UNC Hospitals Department of Radiation Oncology Projected Revenue/Expenses – Project Years 1-3</b>			
<b>Treatments</b>	<b>Project Year 1 FY 2018</b>	<b>Project Year 2 FY 2019</b>	<b>Project Year 3 FY 2020</b>
Projected # of Treatments	26,803	31,265	33,730
Projected Average Charge	\$4,687	\$4,922	\$5,168
Gross Patient Revenue	\$125,638,348	\$153,882,514	\$174,314,496
Deductions from Gross Patient Revenue	(\$79,832,776)	(\$97,779,608)	(\$110,762,442)
Net Patient Revenue	\$45,805,571	\$56,102,907	\$63,552,054
Total Expenses	\$24,478,447	\$26,724,695	\$27,586,332
Net Income	\$21,327,124	\$29,378,212	\$35,965,723

As the table above shows, revenues exceed operating expenses for the department utilizing the proposed CT simulator in each of the first three years of operation.

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

**Conclusion**

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates the availability of sufficient funds for the operating needs of the project and that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges), and operating costs. Therefore, the application is conforming to this criterion.

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



C

UNC Hospitals proposes to acquire an additional CT simulator for use in the Department of Radiation Oncology.

The 2016 SMFP defines the service area for linear accelerators. The Criteria and Standards for Radiation Therapy Equipment (10A NCAC 14C .1900) define the radiation therapy service area as “...a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.” In Section III.5, page 74, the applicant states that it is part of the Orange County linear accelerator service area (Area 14).

The applicant states on page 31 that it operates six linear accelerators and has a certificate of need to develop a seventh in Wake County (Project I.D. #J-10318-14). The applicant also states that it has a certificate of need to relocate an existing linear accelerator to its Hillsborough campus, also in Orange County (Project I.D. #J-11035-15).

According to Table 9G on page 137 of the 2016 SMFP, UNC Hospitals is the only facility operating linear accelerators in Service Area 14. Information in Table 9H on page 139 of the 2016 SMFP documents that during FFY 2014, UNC Hospitals performed 31,214 linear accelerator procedures on five linear accelerators for an average of 6,303 procedures per linear accelerator.

Additionally, page 132 of the 2016 SMFP states the following with regard to CT simulators in support of linear accelerators:

*“One simulator...can serve a facility with three linear accelerators or serve multiple facilities with up to four linear accelerators total.”*

On pages 45-46 of the application, the applicant states that the ratio of CT simulators to linear accelerators is lower at its campus than at any of the other sole service area providers in the state, as shown in the table below:

<b>Current Ratio of CT Simulators to Linear Accelerators – Sole Service Area Providers</b>					
<b>Facility</b>	<b>Service Area</b>	<b>County</b>	<b># of Simulators</b>	<b># of Linear Accelerators</b>	<b>Ratio of Simulators to Linear Accelerators</b>
Watauga Medical Center	3	Watauga	1	1	1.00
Lexington Medical Center	11	Davidson	1	1	1.00
Randolph Hospital	13	Randolph	1	1	1.00
Central Harnett Hospital*	21	Harnett	1	1	1.00
Onslow Radiation Therapy	25	Onslow	1	1	1.00
Alamance Regional Medical Center	15	Alamance	1	2	0.50
UNC Hospitals	14	Orange	1	6	0.17

\*Approved for one linear accelerator and one CT simulator as part of Project I.D. #M-11062-15.

UNC Hospitals adequately demonstrates the need to acquire an additional CT simulator to support its existing radiation oncology service. The discussion regarding analysis of need

found in Criterion (3) is incorporated herein by reference. Consequently, the applicant adequately demonstrates the proposed project would not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the applicant's service area. Therefore, the application is conforming with 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 106-107, the applicant provides the current and proposed Year 2 (FY 2019) staffing for the radiation oncology department, as shown in the table below.

<b>UNC Hospitals Department of Radiation Oncology Current and OY 2 (FY 2019) Proposed Staffing</b>		
<b>Position</b>	<b>Current FTEs</b>	<b>Proposed FTEs</b>
Administrative Support	10.74	12.94
Clinical Support	0.86	0.86
Dosimetrist	7.00	7.55
Nurse	7.45	9.35
Tech	17.44	21.84
Tech Supervisor	1.00	1.00
Physicist	3.00	3.50
Manager	0.50	1.00
<b>Total</b>	<b>48.00</b>	<b>58.05</b>

In Section VII.3(b), page 108, the applicant states that its standard recruitment initiatives will remain in force, and that it will utilize its national recruitment program as well as recruiting potential staff from local and regional community colleges as well as the community at large. In Section VII.8, page 111, the applicant identifies B. Anthony Lindsey, M.D., as the Chief Medical Officer for UNC Hospitals. Exhibit 31 contains a copy of a letter from Dr. Lindsey expressing his support for the project and willingness to continue to serve as Chief Medical Officer. Exhibit 31 also contains copies of letters from physicians and researchers at UNC Hospitals 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, page 34, and Exhibit 5, the applicant documents that all of the necessary ancillary and support services for the proposed services will be provided by the applicant and are available 24 hours per day. In Section V.2, pages 85-86, the applicant states that UNC Hospitals does not have formal transfer agreements because it is an Academic Medical Center and is not required to have formal transfer agreements, but that in general it works with any agency, program, service, or provider that may want to transfer patients to UNC Hospitals. Exhibit 31 contains copies of letters from physicians and researchers 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 with 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 do minor renovations on 646 square feet of existing space originally built to hold a CT simulator. Exhibit 30 contains a letter from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section VIII.2 (pages 115-116) of the application. The applicant provides line drawings in Exhibit 4 showing the area to be renovated. In Section XI.7, pages 130-131, 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 Sections VI.12 and VI.13, page 103, the applicant provides the historical payor mix for FY 2016 for both the radiation oncology department and the entire facility, as shown in the tables below.

<b>UNC Hospitals Historical Payor Mix Entire Facility – FY 2016</b>	
Self-Pay/Indigent/Charity	5.9%
Medicare/Medicare Managed Care	33.3%
Medicaid	28.6%
Commercial/Managed Care	27.2%
Other (Other Gov't)	5.0%
<b>Total</b>	<b>100.0%</b>

<b>UNC Hospitals Historical Payor Mix Radiation Oncology Dept – FY 2016</b>	
Self-Pay/Indigent/Charity	6.0%
Medicare/Medicare Managed Care	39.6%
Medicaid	9.8%
Commercial/Managed Care	38.4%
Other (Other Gov't)	6.1%
<b>Total</b>	<b>100.0%</b>

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.

<b>Percent of Population</b>						
<b>County</b>	<b>% 65+</b>	<b>% Female</b>	<b>% Racial &amp; Ethnic Minority*</b>	<b>% Persons in Poverty**</b>	<b>% &lt; Age 65 with a Disability</b>	<b>% &lt; Age 65 without Health Insurance**</b>
Orange	11%	52%	30%	14%	6%	15%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*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

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 102, 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*

*2015 is estimated to be \$176 million (12.7 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 102, the applicant states that no civil rights complaints have been filed against it or any facilities or services it owns within 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 Sections VI.14 and VI.15, pages 104-105, the applicant provides the projected payor mix for the second operating year following project completion (FY 2019) for both the radiation oncology department and the entire facility, as shown in the tables below.

<b>UNC Hospitals Projected Payor Mix Entire Facility – FY 2019</b>	
Self-Pay/Indigent/Charity	5.9%
Medicare/Medicare Managed Care	33.3%
Medicaid	28.6%
Commercial/Managed Care	27.2%
Other (Other Gov't)	5.0%
<b>Total</b>	<b>100.0%</b>

<b>UNC Hospitals Projected Payor Mix Radiation Oncology Dept – FY 2019</b>	
Self-Pay/Indigent/Charity	6.0%
Medicare/Medicare Managed Care	39.6%
Medicaid	9.8%
Commercial/Managed Care	38.4%
Other (Other Gov't)	6.1%
<b>Total</b>	<b>100.0%</b>

On pages 104 and 105, the applicant states that it projects no change in the payor mix as a result of the proposed project. 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.

C

In Section VI.9, page 101, the applicant describes the range of means by which a person will have access to the proposed services. The information provided is reasonable 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.

C

In Section V.1, pages 83-85, the applicant states that it serves as a clinical teaching site for a broad range of healthcare disciplines and that it offers seminars and educational training programs for community physicians and healthcare workers in addition to providing clinical teaching opportunities to the five health professional schools on its campus and others around the country. The information provided in Section V.1 is reasonable 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

UNC Hospitals proposes to acquire an additional CT simulator for use in the Department of Radiation Oncology.

The 2016 SMFP defines the service area for linear accelerators. The Criteria and Standards for Radiation Therapy Equipment (10A NCAC 14C .1900) define the radiation therapy service area as “...a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.” In Section III.5, page 74, the applicant states that it is part of the Orange County linear accelerator service area (Area 14).

The applicant states on page 31 that it operates six linear accelerators and has a certificate of need to develop a seventh in Wake County (Project I.D. #J-10318-14). The applicant also

states that it has a certificate of need to relocate an existing linear accelerator to its Hillsborough campus, also in Orange County (Project I.D. #J-11035-15).

According to Table 9G on page 137 of the 2016 SMFP, UNC Hospitals is the only facility operating linear accelerators in Service Area 14. Information in Table 9H on page 139 of the 2016 SMFP documents that during FFY 2014, UNC Hospitals performed 31,214 linear accelerator procedures on five linear accelerators for an average of 6,303 procedures per linear accelerator.

Additionally, page 132 of the 2016 SMFP states the following with regard to CT simulators in support of linear accelerators:

*“One simulator...can serve a facility with three linear accelerators or serve multiple facilities with up to four linear accelerators total.”*

On pages 45-46 of the application, the applicant states that the ratio of CT simulators to linear accelerators is lower at its campus than at any of the other sole service area providers in the state, as shown in the table below:

<b>Current Ratio of CT Simulators to Linear Accelerators – Sole Service Area Providers</b>					
<b>Facility</b>	<b>Service Area</b>	<b>County</b>	<b># of Simulators</b>	<b># of Linear Accelerators</b>	<b>Ratio of Simulators to Linear Accelerators</b>
Watauga Medical Center	3	Watauga	1	1	1.00
Lexington Medical Center	11	Davidson	1	1	1.00
Randolph Hospital	13	Randolph	1	1	1.00
Central Harnett Hospital*	21	Harnett	1	1	1.00
Onslow Radiation Therapy	25	Onslow	1	1	1.00
Alamance Regional Medical Center	15	Alamance	1	2	0.50
UNC Hospitals	14	Orange	1	6	0.17

\*Approved for one linear accelerator and one CT simulator as part of Project I.D. #M-11062-15.

The applicant does not propose to add services or acquire equipment for which there is a need determination methodology in the 2016 SMFP.

In Section V.7, pages 93-94, the applicant discusses how any enhanced competition in the service area will have a positive impact on the cost-effectiveness, quality, and access to the proposed services, stating:

- The proposed CT simulator is being developed in existing space that requires only minor renovations;
- The proposed CT simulator will allow continued provision of high quality services to patients in the service area; and
- The proposed CT simulator will promote access to healthcare services since every patient receiving radiation therapy is required to use the CT simulator to plan treatment and growth in the utilization of the radiation oncology program is expected.



See also Sections II, III, V, VI, and VII 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 discussion regarding access found in Criterion (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.

### C

In Section I.12, pages 13-21, the applicant lists the facilities and programs owned by UNC Hospitals. UNC Hospitals owns or manages nine licensed healthcare facilities in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, incidents occurred at three of the nine licensed facilities within the eighteen months immediately preceding submission of the application through the date of this decision related to quality of care. As of the date of this decision, the Agency is waiting for CMS final determination on one facility and waiting for a Plan of Correction from the other two facilities. 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 Rex and the other eight facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic

medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA

In Appendix F, page 440, of the 2016 SMFP, UNC Hospitals is listed as an Academic Medical Center Teaching Hospital as of August 8, 1983. The Criteria and Standards for Radiation Therapy Equipment promulgated in 10A NCAC 14C .1900 contains no provisions applicable to this review. Therefore, this criterion is not applicable in this review.