

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 28, 2017

Findings Date: September 28, 2017

Project Analyst: Mike McKillip

Team Leader: Lisa Pittman

Project ID #: J-11365-17

Facility: University of North Carolina Hospitals at Chapel Hill

FID #: 923517

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Acquire proton therapy equipment

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

University of North Carolina Hospitals at Chapel Hill [**UNC Hospitals**] proposes to acquire proton therapy equipment to be installed at the North Carolina Cancer Hospital on the campus of UNC Hospitals in Chapel Hill.

Need Determination and Policies

There are no need determinations in the 2017 State Medical Facilities Plan (SMFP) applicable to the acquisition of proton therapy equipment. However, Policy GEN-4 is applicable.

Policy GEN-4

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, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B.11, pages 28, the applicant states:

“UNC Hospitals will develop and implement an Energy Efficiency and Sustainability plan for the proposed project that conforms to or exceeds the energy efficiency and water conservation standards incorporated in the latest editions of the NC State Building Codes. The plan shall not adversely affect patient or resident health, safety, or infection control.”

The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

In summary, the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4. 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.

C

The applicant, UNC Hospitals, proposes to acquire proton therapy equipment to be installed at the North Carolina Cancer Hospital on the campus of UNC Hospitals in Chapel Hill. In Section C.1, pages 37-42, the applicant describes the proposed project as follows:

“The proposed project involves the acquisition of a Proteus One proton therapy system from IBA (the equipment vendor), which will fill the unmet need for proton therapy in the state. Proton therapy is a form of external beam radiation therapy (EBRT) in which a cyclotron uses electricity to generate beams of protons to attack cancer cells. Unlike a linear accelerator, which per the definition in the CON statute at §131E-176(14g) is used to generate photons (X-rays) or electrons to treat cancer cells, a proton system generates protons, a different and heavier particle than what a linear accelerator is capable of generating. While both types of equipment function similarly, as described above, a key difference is that photon beams from a linear accelerator typically deliver most of the radiation dose prior to reaching the tumor (particularly if the tumor lies deep beneath layers of other tissues), and also deliver a significant amount of radiation dose to normal tissues after the beam traverses the tumor (i.e. after exiting the tumor the beam continues to deliver dose to these ‘downstream’ normal tissues.) Conversely, proton beams can be more effectively target the radiation dose delivery to a precise depth beneath the surface of the body where the tumor resides. The amount of radiation dose from the proton beam peak as the protons slow and are stopped at the targeted depth, allowing the majority of the radiation to impact the tumor, not the healthy tissue surrounding it....

While the size of the treatment room is similar to other types of EBRT, such as linear accelerators, the overall size of the system is much larger due to the components required to generate, accelerate and control the protons. As shown in the drawing [on page 41 of the application], the entire system, including the cyclotron, treatment room and control room, spans multiple rooms. The system requires three floors of space, plus a fourth floor ‘penthouse’ for HVAC systems, totaling nearly 12,000 square feet of new construction. ... Due to the size requirements for the system and the lack of unused space on the UNC Hospitals campus, particularly in proximity to the N.C. Cancer Hospital, UNC Hospitals proposes to develop the proton system in the parking lot located in front of the N.C. Cancer Hospital. ... The new three-story construction will connect to the existing N.C. Cancer Hospital on the ground floor via a connecting corridor.”

Patient Origin

The 2017 SMFP does not define a service area for proton therapy equipment. In Section C.3, pages 45-46, the applicant provides the projected patient origin for the first three operating years (FY2022-FY2024), as shown in the table below.

Projected Patient Origin for Proton Therapy Services at UNC Hospitals

County	Percent of Total Patients	PY 1 FY2022 Patients	PY 2 FY2023 Patients	PY 3 FY2024 Patients
Orange	16.0%	16	24	32
Wake	14.2%	14	21	28
Chatham	9.1%	9	13	18
Alamance	7.9%	8	12	16
Durham	6.4%	6	9	13
Lee	5.1%	5	8	10
Cumberland	4.5%	4	7	9
Guilford	3.2%	3	5	6
Harnett	2.7%	3	4	5
Nash	2.3%	2	3	5
New Hanover	1.6%	2	2	3
Sampson	1.6%	1	2	3
Johnston	1.4%	1	2	3
Caswell	1.3%	1	2	2
Robeson	1.2%	1	2	2
Person	1.1%	1	2	2
All Other*	20.4%	22	30	40
TOTAL	100.0%	99	148	197

Source: Tables on pages 45-47 of the application.

*The applicant lists the counties included in the “All Other” category on pages 45-47 of the application.

In Section C.3, page 47, the applicant states, “*UNC Hospitals conservatively projects its patient origin for the proposed service to mirror that of its existing radiation therapy program.*” The applicant’s projected patient origin for the proposed project is consistent with the historical patient origin for the radiation therapy services as reported in Section C.2, pages 42-44. The applicant adequately identified the population proposed to be served.

Analysis of Need

In Section C.4 of the application, the applicant describes the factors which it states supports the need for the proposed project, including:

- The lack of proton therapy equipment in North Carolina (pp. 48-53).
- The current and projected cancer cases in North Carolina (p. 53)
- The number of patients who could benefit from proton therapy (pp. 54-58)
- The historical growth in the utilization of radiation therapy services at UNC Hospitals from FY2014 to FY2016 (pp. 58-59).
- The need to advance proton therapy research and teaching (pp. 60-68).

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

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the proposed proton therapy equipment through the first three years of operation following completion of the project, which is summarized below.

Projected Utilization of Proton Therapy Services at UNC Hospitals

	PY 1 FY2022	PY 2 FY2023	PY 3 FY2024
Number of units	1	1	1
Patients	99	148	197
Total Treatments	2,673	3,996	5,319
Total ESTVs	5,346	7,992	10,638

As shown in the above table, the applicant projects it will treat 99 patients with the proposed proton therapy equipment in the first year of operation, and 197 patients in the third operating year of the project. In Section C.6, pages 69-70, the applicant projects the proposed proton therapy equipment will have the maximum capacity to serve 197 patients, annually, based on the assumption the equipment is operational 12 hours per day, five days per week.

In Section Q, Form C, the applicant describe its assumptions and methodology for projecting utilization of the proton therapy equipment at UNC Hospitals, as summarized below.

Step 1: Project Cancer Cases Appropriate for Proton Therapy

Based on available research and estimates provided by the faculty physicians at UNC Hospitals, the applicant projects that 6.7 percent of all cancer cases are appropriate for treatment by proton therapy. The applicant applied that percentage to its projections of total cancer cases in the state, based on historical cancer incidence data from the State Center for Health Statistics, as summarized in the table below:

Projected Cancer Cases Appropriate for Proton Therapy

Year	Total Cancer Cases	Percent Appropriate for Proton Therapy	Proton Therapy-Appropriate Cases
2018	60,173	6.7%	4,032
2019	61,009	6.7%	4,088
2020	61,856	6.7%	4,144
2021	62,715	6.7%	4,202
2022	63,585	6.7%	4,260
2023	64,468	6.7%	4,316
2024	65,364	6.7%	4,379

Source: Table on page 2 of Form C in Section Q of the application.

Step 2: Project Proton Therapy Cases to be Treated at UNC Hospitals

UNC Hospitals assumes that it will treat 5.6 percent of the total projected cancer cases that are appropriate for proton therapy. In Section Q, page 3, the applicant states,

“According to Table 9G in the 2017 SMFP, and as presented in Section C.4, UNC Hospitals performed more radiation therapy treatments, measured in ESTVs, than any other single site in the state. Specifically, UNC Hospitals provided 31,962 of the 574,069 ESTVs performed statewide, or 5.6 percent. Used as a proxy for market share, it is clear that UNC Hospitals’ radiation oncology service has a broad statewide reach, even before implementation of the proposed project. ... Although UNC Hospitals would be the first and potentially only proton therapy center in the state if the proposed project is approved, assuming it only serves the same percentage of proton therapy patients that it does linear accelerator patients, 5.6 percent, would result in the following number of proton therapy patients:

<i>Year</i>	<i>Statewide Proton-Appropriate Cases</i>	<i>Percent Served at UNC Hospitals</i>	<i>Proton Cases at UNC Hospitals</i>
2018	4,032	5.6%	226
2019	4,088	5.6%	229
2020	4,144	5.6%	232
2021	4,202	5.6%	235
2022	4,260	5.6%	239
2023	4,316	5.6%	242
2024	4,379	5.6%	245

Step 3: Project Utilization at UNC Hospitals in First Three Operating Years

In Section Q, pages 3-4, the applicant states,

“Given the factors discussed above, as well as the need for the project presented in Section C.4 of the application, UNC Hospitals believes that it is reasonable to assume that it will serve 5.6 percent of the total proton therapy cases statewide. However, as noted in Section C.6(b) and in response to the rules for radiation therapy equipment, UNC Hospitals estimates that the proposed equipment will have a capacity of 197 patients per year. While it may choose to increase staffing and hours of operation in the future, UNC Hospitals believes that it has proposed a conservative and prudent approach to developing this new technology in the state. The projected number of patients in the third full fiscal year of the project will therefore be only 197. ... Further, while UNC Hospitals has an existing high volume cancer program that takes in new cancer patients on a daily basis, it does not project that it will reach full capacity of the proposed proton unit within the first year. Rather, it projects that it will serve 50 percent of this in year one (or 99 patients), 75 percent in year two (148 patients) and 100 percent in year three (197 patients)....

According to equipment vendor, most patients receive 27 treatments (fractions). This is consistent with the number of treatments for linear accelerator patients as well. The performance standards for radiation therapy equipment suggest this ratio, by requiring new linear accelerators to demonstrate utilization of 6,750 ESTV treatments or 250 patients. Since most treatments performed on standard linear accelerators (simple,

intermediate, complex or IMRT) have a weight of 1.0 ESTV each, the assumed number of treatments per patient is thus 27 (6,750 ESTVs / 250 patients = 27 standard treatments per patient).

As defined in the radiation therapy rules at 10A NCAC 14 C .1901(16)(d), proton treatments are considered a 'special technique' with a weight of 2.0 ESTVs per treatment. Applying this weighting to the cases projected above results in the following number of projected ESTVs:

<i>Year</i>	<i>Proton Cases at UNC Hospitals Cases</i>	<i>Total Treatments at 27 per Patient</i>	<i>Total ESTVs at 2.0 per Proton Treatment</i>
<i>2022</i>	<i>99</i>	<i>2,673</i>	<i>5,346</i>
<i>2023</i>	<i>148</i>	<i>3,996</i>	<i>7,992</i>
<i>2024</i>	<i>197</i>	<i>5,319</i>	<i>10,638</i>

As discussed above, the applicant projects utilization of the proposed proton therapy equipment based on statewide cancer incidence data and the historical utilization of UNC Hospitals linear accelerator services. Exhibit I.2 contains letters from physicians expressing support for the proposed project. Projected utilization of the proton therapy equipment at UNC Hospitals is based on reasonable and adequately supported assumptions. Therefore, the applicant adequately demonstrates the need to acquire one unit of proton therapy equipment at UNC Hospitals in Chapel Hill.

Access

In Section C.10, page 72, the applicant states 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 L.1, page 114, the applicant reports that 53.8 percent of oncology services at UNC Hospitals were provided to Medicare or Medicaid recipients in FY2016. In Section L.3, page 116, the applicant projects that 53.8 percent of proton therapy cases will be provided to Medicare or Medicaid recipients at UNC Hospitals in the second year of operation following completion of the project. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

Conclusion

In summary, the applicant adequately identified the population to be served, demonstrates the need the population has for the project and adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons,

racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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.

C

In Section E.2, pages 85-86, the applicant describes the following alternatives:

- Acquire another type of equipment – The applicant states this was not an effective alternative due to advantages of the vendor’s experience and the cost of acquisition in comparison to other types of equipment.
- Develop the project at another location – The applicant states this was not an effective alternative due to the fact that patients who are best candidates for proton therapy are pediatric patients and complex cases that would most likely be treated at the academic medical center in Chapel Hill. Also, most of UNC Hospitals’ existing radiation therapy services are currently located in Chapel Hill, which is centrally located within the state.
- Develop the project as a joint venture – The applicant states this was not an effective alternative because it was unable to identify a suitable joint venture partner.

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 applicable statutory review criteria, and thus, the application is approvable. An application that cannot be approved is not an effective alternative.

In summary, the applicant adequately demonstrates that this 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 acquire one unit of proton therapy equipment.**
- 3. 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 Q of the application and that would otherwise require a certificate of need.**

4. **University of North Carolina Hospitals at Chapel Hill shall develop and implement an energy efficiency and sustainability plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
 5. **No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, University of North Carolina Hospitals at Chapel Hill shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. **Payor mix for the services authorized in this certificate of need.**
 - b. **Utilization of the services authorized in this certificate of need.**
 - c. **Revenues and operating costs for the services authorized in this certificate of need.**
 - d. **Average gross revenue per unit of service.**
 - e. **Average net revenue per unit of service.**
 - f. **Average operating cost per unit of service.**
 6. **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

The applicant, UNC Hospitals, proposes to acquire proton therapy equipment to be installed at the North Carolina Cancer Hospital on the campus of UNC Hospitals in Chapel Hill.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant states the total capital cost for the proposed project is projected to be as follows:

UNC Hospitals Proton Therapy Project Capital Cost

Cost Category	Projected Capital Cost
Site Preparation	\$1,109,079
Construction	\$8,918,544
Architect/Engineering Fees	\$1,203,315
Medical Equipment	\$25,858,585
Furniture	\$4,000
Other (parking, mgmt. fee, etc.)	\$1,989,740
TOTAL CAPITAL COST	\$39,080,263

Source: Section Q, Form F.1a of the application.

In Section F.3, pages 90-91, the applicant states that no start-up or initial operating expenses will be required to develop the project.

Availability of Funds

In Section F.2, page 89, the applicant states that the \$39,080,263 in project capital costs for the proposed proton therapy facility will be funded by the accumulated reserves of UNC Hospitals. In Exhibit F.2, the applicant provides a letter dated June 15, 2017, from the Executive Vice President and Chief Financial Officer for UNC Hospitals documenting its intention to provide accumulated reserves in the amount of \$39,080,263 to finance the proposed project. Exhibit F.2.2 contains a copy of the audited financial statements for UNC Hospitals for the years ended June 30, 2015 and 2016 which indicate that UNC Hospitals had \$190 million in cash and cash equivalents as of June 30, 2016. The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statements (Form F.4b), the applicant projects that operating revenue will exceed expenses in the first three full fiscal years of operation of the project, as shown in the table below.

Projected Revenue and Expenses for Radiation Oncology Services at UNC Hospitals

	PY1 FY2022	PY2 FY2023	PY3 FY2024
Total Treatments*	38,107	39,060	40,036
Total Gross Revenue (Charges)	\$214,887,019	\$229,201,037	\$243,942,904
Total Net Revenue	\$76,364,226	\$80,602,934	\$84,997,629
Average Net Revenue/Treatment	\$2,004	\$2,063	\$2,123
Total Operating Expenses	\$42,429,993	\$45,042,536	\$48,305,798
Average Operating Expense/Treatment	\$1,197	\$1,285	\$1,391
Net Income (Loss)	\$33,934,233	\$35,560,398	\$36,691,830

*Includes both linear accelerator treatments and proton therapy treatments.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application

for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

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

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

C

The applicant, UNC Hospitals, proposes to acquire proton therapy equipment to be installed at the North Carolina Cancer Hospital on the campus of UNC Hospitals in Chapel Hill. The 2017 SMFP does not define a service area for proton therapy equipment. In Section G, page 96, the applicant states, *“There is no existing or approved equipment in North Carolina capable of providing proton therapy.”*

The applicant adequately demonstrates the need to acquire the proton therapy equipment. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. Therefore, the applicant adequately demonstrates that the proposal would not result in unnecessary duplication of existing or approved services or facilities. Consequently, the application is conforming to this criterion.

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

C

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed proton therapy services at UNC Hospitals for each of the first three operating years, as summarized in the table below.

Position	Proposed Staffing FTE Positions
Medical Resident	1.0
Medical Physicist	1.5
Dosimetrist	1.5
Radiation Therapist	4.0
Clinical Nurse III	1.5
Billing/Coding	2.0
Administrator	1.0
Administrative Support	1.0
TOTAL	13.5

Source: Form H in Section Q of the application.

In Section H.2, pages 98-99, the applicant describes its experience and process for recruiting and retaining staff. In Section H.4, page 100, the applicant identifies Lawrence Marks, M.D., as the Medical Director for radiation oncology services at UNC Hospitals. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Section I.1, pages 103-104, the applicant identifies and describes the manner in which it will provide the necessary ancillary and support services. Exhibit I.2 of the application contains copies of letters from physicians expressing support for the proposed project. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services 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

The applicant, UNC Hospitals, proposes to acquire proton therapy equipment and develop a proton therapy treatment facility in a new addition connected to the existing N.C. Cancer Hospital on the main hospital campus in Chapel Hill. The proposed new addition will be 11,818 square feet, and the project will also include 2,460 square feet of renovations to the existing facility. Exhibit F.1-2 contains a certified cost estimate from an architect that estimates construction costs that are consistent with the project capital cost projections provided by the applicant in Section Q, Form F.1a of the application. In Section K.4, pages 108-109, 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 for the proposed addition and renovations, and that the construction cost will not unduly increase costs and charges for health services. Therefore, the application is conforming to this criterion.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L.1, page 114, the applicant reports the following payor mix percentages for radiation oncology services at UNC Hospitals for FY2016.

Payor Category	Radiology Oncology Services as Percent of Total
Self-Pay/Indigent/Charity	4.9%
Medicare	43.5%
Medicaid	10.3%
Commercial/Managed Care	35.8%
Other (Includes other government)	5.5%
Total	100.0%

Source: Table on page 114 of the application.

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

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
	2016 Estimate	2016 Estimate	2016 Estimate	2015 Estimate	2011-2015	2015 Estimate
Orange	12%	52%	31%	14%	6%	10%
Wake	11%	51%	40%	11%	6%	10%
Durham	12%	52%	58%	17%	7%	14%
Chatham	26%	52%	28%	12%	8%	15%
Lee	16%	51%	41%	17%	10%	16%
Statewide	16%	51%	37%	16%	10%	13%

Source: <http://www.census.gov/quickfacts/table> Latest Data 7/1/16 as of 8/22/17

*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., V2016) refers to the final year of the series (2010 thru 2016). 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 adequately demonstrates that it currently provides 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 L.2, page 114, the applicant states,

“UNC Hospitals has long since satisfied its ‘free care’ obligation under the Hill-Burton Act. ... 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 L.2, page 115, the applicant states that no civil rights access complaints have been filed against any UNC Hospitals facility 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 L.3, page 116, the applicant projects the following payer mix for proton therapy services during the second operating year (FY2023):

Payor Category	Proton Therapy Services as Percent of Total
Self-Pay/Indigent/Charity	4.9%
Medicare	43.5%
Medicaid	10.3%
Commercial/Managed Care	35.8%
Other (Includes other government)	5.5%
Total	100.0%

Source: Table on page 116 of the application.

On page 116, the applicant states projected payer mix is based on the historical payer mix for radiation therapy services at UNC Hospitals. The applicant adequately demonstrates that medically underserved populations will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section L.5, pages 117-118, the applicant describes the range of means by which a person will have access to UNC Hospitals' proton therapy services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section M.1, page 119, the applicant states that UNC Hospitals serves a clinical training site for a broad range of health professional training programs. The applicant provides a list of training programs with which UNC Hospitals has relationships in Section M.1, pages 119-120. The information provided is reasonable and adequately supports a determination that the application is conforming to this criterion.

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

C

The applicant, UNC Hospitals, proposes to acquire proton therapy equipment to be installed at the North Carolina Cancer Hospital on the campus of UNC Hospitals in Chapel Hill. The 2017 SMFP does not define a service area for proton therapy equipment. The applicant states that there are currently no providers of proton therapy services located in North Carolina.

In Section N.2, pages 122-125, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

"The proposed project will have a positive impact on cost effectiveness in several ways. First, patients from North Carolina must currently travel out of state if their condition warrants treatment using proton therapy. ... Next, the proposed project involves the development of one of the lowest cost proton therapy systems on the market today. ... Finally, as a state-owned healthcare system dedicated to effective clinical practice,

research, and teaching, the proposed project will allow UNC Hospitals to provide appropriate clinical care while the School of Medicine and UNC's other professional schools [sic] to advance research and teaching using the same equipment....

The proposed project will provide access to high quality proton therapy services within North Carolina for the first time. As noted in Section O, the Department of Radiation Oncology at UNC has a robust and innovative quality assurance programs that is nationally and internationally recognized....

As noted above, UNC Hospitals operates North Carolina's only state-owned comprehensive, full service hospital-based radiation oncology program, and it has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status or lack of medical insurance."

The information in the application is reasonable and credible and adequately demonstrates that any enhanced competition in the service area includes a positive impact on 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 proposed project and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- ◆ The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- ◆ The applicant demonstrates that it will continue to provide access to medically underserved populations. The discussion regarding access found in Criterion (13) is incorporated herein by reference.

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

The University of North Carolina Health Care System owns or manages nine licensed healthcare facilities in North Carolina, including UNC Hospitals at Chapel Hill. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, Rex Hospital, Caldwell Memorial Hospital and Wayne Memorial Hospital are currently awaiting final determinations from CMS regarding their compliance with a CMS Condition of Participation. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, none of the other facilities is currently out of compliance with a CMS Condition of Participation, nor have any other 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 The University of North Carolina Health Care System. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at UNC Health Care System 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.

C

The application is conforming with all applicable Criteria and Standards for Radiation Therapy Equipment. The specific criteria are discussed below.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a linear accelerator shall demonstrate that each of the following standards will be met:

- (1) an applicant's existing linear accelerators located in the proposed radiation therapy service area performed at least 6,750 ESTV treatments per machine or served at least 250 patients per machine in the twelve months prior to the date the application was submitted;*
- (2) each proposed new linear accelerator will be utilized at an annual rate of 250 patients or 6,750 ESTV treatments during the third year of operation of the new equipment; and*
- (3) an applicant's existing linear accelerators located in the proposed radiation therapy service area are projected to be utilized at an annual rate of 6,750 ESTV treatments or 250 patients per machine during the third year of operation of the new equipment.*

-NA- The applicant is not proposing to acquire a linear accelerator.

(b) A linear accelerator shall not be held to the standards in Paragraph (a) of this Rule if the applicant provides documentation that the linear accelerator has been or will be used exclusively for clinical research and teaching.

-NA- The applicant is not proposing to acquire a linear accelerator.

(c) An applicant proposing to acquire radiation therapy equipment other than a linear accelerator shall provide the following information:

- (1) *the number of patients who are projected to receive treatment from the proposed radiation therapy equipment, classified by type of equipment, diagnosis, treatment procedure, and county of residence; and*
- C- The applicant provides the number of patients who are projected to receive treatment with the proposed proton therapy equipment by diagnosis and treatment procedure in Section C.11, pages 77-78. The applicant provides number of patients who are projected to receive treatment with the proposed proton therapy equipment by county of residence in Section C.3, pages 45-47.
- (2) *the maximum number and type of procedures that the proposed equipment is capable of performing.*
- C- The applicant provides the projected maximum number and types of procedures that the proton therapy equipment is capable of performing in Section C.11, page 79.
- (d) *The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.*
- C- The applicant documented the assumption and methodology supporting utilization of the proton therapy equipment in Section Q, Form C.