

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: May 6, 2020

Findings Date: May 6, 2020

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: J-11864-20

Facility: University of North Carolina Hospitals

FID #: 923517

County: Orange

Applicant: University of North Carolina Hospitals at Chapel Hill

Project: Acquire a MR simulator pursuant to Policy AC-3

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 (hereinafter referred to as UNC Hospitals or “the applicant”) proposes to acquire a MR simulator pursuant to Policy AC-3.

Need Determination

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 2020 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

There are two policies in the 2020 SMFP applicable to this review: *Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy AC-3

Policy AC-3: Exemption from Plan Provisions for Certain Academic Medical Center Teaching Hospital Projects states:

“Projects for which certificates of need are sought by Academic Medical Center Teaching Hospitals may qualify for exemption from the need determinations of this document. The Healthcare Planning and Certificate of Need Section shall designate as an Academic Medical Center Teaching Hospital any facility whose application for such designation demonstrates the following characteristics of the hospital:

- 1. Serves as a primary teaching site for a school of medicine and at least one other health professional school, providing undergraduate, graduate and postgraduate education.*
- 2. Houses extensive basic medical science and clinical research programs, patients and equipment.*
- 3. Serves the treatment needs of patients from a broad geographic area through multiple medical specialties.*

[Note: The following paragraph is the second paragraph referenced in the questions that follow this policy.]

Exemption from the provisions of need determinations of the North Carolina State Medical Facilities Plan shall be granted to projects submitted by Academic Medical Center Teaching Hospitals designated prior to January 1, 1990 provided the projects are necessary to meet one of the following unique academic medical needs:

- 1. Necessary to complement a specified and approved expansion of the number or types of students, residents or faculty that are specifically required for an expansion of students or residents, as certified by the head of the relevant associated professional school; the applicant shall provide documentation that the project is consistent with any relevant standards, recommendations or guidance from specialty education accrediting bodies; or*
- 2. With respect to the acquisition of equipment, is necessary to accommodate the recruitment or retention of a full-time faculty member who will devote a majority of his or her time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within the academic medical center teaching hospital or medical school; or*

3. *Necessary to accommodate patients, staff or equipment for a specified and approved expansion of research activities, as certified by the head of the entity sponsoring the research; and including, to the extent applicable, documentation pertaining to grants, funding, accrediting or other requirements, and any proposed clinical application of the asset; or*
4. *Necessary to accommodate changes in requirements of specialty education accrediting bodies, as evidenced by copies of documents issued by such bodies.*

A project submitted by an Academic Medical Center Teaching Hospital under this policy that meets one of the above conditions shall demonstrate that the Academic Medical Center Teaching Hospital's teaching or research need for the proposed project cannot be achieved effectively at any non-Academic Medical Center Teaching Hospital provider which currently offers and has capacity within the service for which the exemption is requested and which is within 20 miles of the Academic Medical Center Teaching Hospital.

The Academic Medical Center Teaching Hospital shall include in its application an analysis of the cost, benefits and feasibility of engaging that provider in a collaborative effort that achieves the academic goals of the project as compared with the certificate of need application proposal. The Academic Medical Center Teaching Hospital shall also provide a summary of a discussion or documentation of its attempt to engage the provider in discussion regarding its analysis and conclusions.

The Academic Medical Center Teaching Hospital shall include in its application a discussion of any similar assets within 20 miles that are under the control of the applicant or the associated professional school and the feasibility of using those assets to meet the unique teaching or research needs of the Academic Medical Center Teaching Hospital.

For each of the first five years of operation the approved applicant shall submit to Certificate of Need a detailed description of how the project achieves the academic requirements of the appropriate section(s) of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.

Applicants who are approved for Policy AC-3 projects after January 1, 2012 shall report those Policy AC-3 assets (including beds, operating rooms and equipment) on the appropriate annual license renewal application or registration form for the asset. The information to be reported for the Policy AC-3 assets shall include: (a) inventory or number of units of AC-3 Certificate of Need-approved assets (including all beds, operating rooms and equipment); (b) the annual volume of days, cases or procedures performed for the reporting year on the Policy AC-3 approved asset; and (c) the patient origin by county. Neither the assets under (a) above nor the utilization from (b) above shall be used in the annual State Medical Facilities Plan need determination formulas, but both the assets and the utilization will be available for informational purposes to users of the State Medical Facilities Plan.

This policy does not apply to a proposed project or the portion thereof that is based solely upon the inability of the State Medical Facilities Plan methodology to accurately project need for the proposed service(s), due to documented differences in patient treatment times that are attributed to education or research components in the delivery of patient care or to differences in patient acuity or case mix that are related to the applicant's academic mission. However, the applicant may submit a petition pursuant to the State Medical Facilities Plan Petitions for Adjustments to Need Determinations process to meet that need or portion thereof.

Policy AC-3 projects are required to materially comply with representations made in the certificate of need application regarding academic based need. If an asset originally developed or acquired pursuant to Policy AC-3 is no longer used for research and/or teaching, the Academic Medical Center Teaching Hospital shall surrender the certificate of need."

The Division of Health Service Regulation designated UNC Hospitals as an academic medical center teaching hospital prior to January 1, 1990. In Section B.3, pages 14-18, and Exhibits B.3-1 and B.3-2, the applicant provides documentation that the acquisition of the proposed MR simulator is necessary to accommodate the recruitment and retention of full-time faculty members that devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within UNC Hospitals, that the proposed project is necessary to accommodate the expansion of research activities using MR simulation-based radiation therapy treatment, and that there are no non-academic medical center teaching hospital providers within 20 miles that offer MR simulation-based radiation therapy treatment. The applicant adequately demonstrates that the proposed project is consistent with the requirements of Policy AC-3.

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 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.11, pages 24-25, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the proposal is consistent with Policy AC-3 and Policy GEN-4 for the following reasons:
 - The applicant adequately documents that the acquisition of the proposed MR simulator is necessary to accommodate the recruitment and retention of full-time faculty members that devote a majority of their time to the combined activities of teaching (including teaching within the clinical setting), research, administrative or other academic responsibilities within UNC Hospitals;
 - The applicant adequately documents that the proposed project is necessary to accommodate the expansion of research activities using MR simulation-based radiation therapy treatment; and
 - The applicant adequately documents there are no non-academic medical center teaching hospital providers within 20 miles that offer MR simulation-based radiation therapy treatment.
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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 a MR simulator pursuant to Policy AC-3. The proposed equipment will be located in renovated space on the hospital's main campus in Chapel Hill. In Section C.1, page 29, the applicant describes the project as follows:

“UNC Hospitals proposes to acquire a Siemens MAGNETOM Vida 3T MRI for Radiation Oncology. Please see Exhibit C.1-2 for a vendor quote for the proposed equipment, which outlines its specifications in detail. The proposed MR simulator will be utilized for simulation and treatment planning for patients prior to linear accelerator and brachytherapy treatments. The proposed project will be developed in 1,069 square feet of existing space that will be renovated to house the proposed MR simulator. The existing space is currently occupied by one of UNC Hospitals' two existing CT simulators, which UNC Hospitals plans to remove from service with the development of this proposed project. As such, following completion of the proposed project, UNC Hospitals will operate one CT simulator and one MR simulator.”

Patient Origin

N.C.G.S. §131E-176(24a) states: “Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.” The 2020 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. Section 10A NCAC 14C .1901, Criteria and Standards for Radiation Therapy Equipment, subsection (13) states, “‘Radiation therapy service area’ means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.” In Chapter 17, Table 17C-4, page 408 of the 2020 SMFP, Orange County is included in Linear Accelerator Service Area 14, which also includes Chatham County. Providers may serve residents of counties not included in their service area.

In Sections C.2 and C.3, pages 30-31, the applicant provides the historical (FY2019) patient origin for radiation oncology services at UNC Hospitals, and the projected patient origin for the first three full fiscal years of operation (FY2022-FY2024) of the proposed project, as shown in the following tables:

**Historical Patient Origin
 UNC Hospitals Radiation Oncology FY2019**

COUNTY	LAST FULL FY (7/1/18 – 6/30/19)	
	# PATIENTS	% OF TOTAL
Orange	264	15.5%
Wake	245	14.4%
Chatham	120	7.1%
Alamance	118	6.9%
Cumberland	106	6.3%
Durham	94	5.5%
Lee	56	3.3%
Moore	46	2.7%
Harnett	36	2.1%
Other*	615	36.2%
Total	1,699	100.0%

*Applicant states the "Other" category includes Alexander, Alleghany, Anson, Ashe, Avery, Beaufort, Bertie, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Caswell, Catawba, Cleveland, Columbus, Craven, Dare, Davidson, Duplin, Edgecombe, Forsyth, Franklin, Gaston, Gates, Graham, Granville, Greene, Guilford, Halifax, Haywood, Henderson, Hertford, Hoke, Hyde, Iredell, Jackson, Johnston, Jones, Lenoir, Madison, Martin, McDowell, Mecklenburg, Mitchell, Montgomery, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Person, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Sampson, Scotland, Stanly, Surry, Swain, Transylvania, Tyrrell, Union, Vance, Warren, Watauga, Wayne, Wilkes, Wilson, and Yancey counties, as well as other states.

Projected Patient Origin

COUNTY	1 st Full FY FY2022		2 nd Full FY FY2023		3 rd Full FY FY2024	
	# Pts	% of Total	# Pts	% of Total	# Pts	% of Total
Orange	355	15.5%	373	15.5%	392	15.5%
Wake	329	14.4%	346	14.4%	364	14.4%
Chatham	161	7.1%	170	7.1%	179	7.1%
Alamance	158	6.9%	166	6.9%	175	6.9%
Cumberland	143	6.3%	151	6.3%	158	6.3%
Durham	126	5.5%	132	5.5%	139	5.5%
Lee	76	3.3%	80	3.3%	84	3.3%
Moore	62	2.7%	65	2.7%	68	2.7%
Harnett	49	2.1%	51	2.1%	54	2.1%
Other*	827	36.2%	870	36.2%	915	36.2%
Total	2,285	100%	2,404	100%	2,528	100%

Applicant states the “Other” category includes Alexander, Alleghany, Anson, Ashe, Avery, Beaufort, Bertie, Bladen, Brunswick, Buncombe, Burke, Cabarrus, Caldwell, Carteret, Caswell, Catawba, Cleveland, Columbus, Craven, Dare, Davidson, Duplin, Edgecombe, Forsyth, Franklin, Gaston, Gates, Graham, Granville, Greene, Guilford, Halifax, Haywood, Henderson, Hertford, Hoke, Hyde, Iredell, Jackson, Johnston, Jones, Lenoir, Madison, Martin, McDowell, Mecklenburg, Mitchell, Montgomery, Nash, New Hanover, Northampton, Onslow, Pamlico, Pasquotank, Pender, Perquimans, Person, Pitt, Polk, Randolph, Richmond, Robeson, Rockingham, Rowan, Rutherford, Sampson, Scotland, Stanly, Surry, Swain, Transylvania, Tyrrell, Union, Vance, Warren, Watauga, Wayne, Wilkes, Wilson, and Yancey counties, as well as other states.

In Section C.3(c), page 31, the applicant states that the projected patient origin is based on the historical patient origin for radiation oncology services at UNC Hospitals. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 32-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The historical growth in utilization of radiation therapy services as UNC Hospitals from FY2017 to FY2020 (page 32).
- The superiority of MR simulators over CT simulators in terms of image quality and clarity, and current high utilization of the existing MRI scanners at UNC Hospitals, which makes them unavailable for simulation purposes (pages 33-34).
- The clinical benefits of MR simulation in treatment planning for radiation therapy services (pages 34-35).
- The advantages of MR simulation to faculty and research programs at UNC Hospitals (pages 35-39).

The information is reasonable and adequately supported for the following reasons:

- The applicant provides reasonable and adequately supported information to support its assertions regarding the clinical advantages of MR simulation for radiation oncology services.
- The applicant provides historical data to support its assumptions regarding the projected utilization of UNC Hospital’s radiation therapy services by the proposed service area.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization, as summarized in the following table.

UNC Hospitals			
MR Simulator Projected Utilization			
	FY 1 FY2022	FY 2 FY2023	FY 3 FY 2024
MR Simulator Procedures	938	968	998

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Project growth in linear accelerator utilization based on historical utilization - The applicant states that it calculated the average annual growth rate of 11 percent for linear accelerator utilization based on data from FY2017 to FY2020, and assumes the future average annual growth of the hospital’s linear accelerator services will be half that rate, or 5.5 percent, through the first three operating years of the proposed project.

Identify the linear accelerator patients that would be appropriate for MR simulation - The applicant states that, based on the clinical expertise of faculty and staff, it projected the percentage of linear accelerator patients that would benefit from MR simulation rather than CT simulation, and applied that percentage to the projected number of linear accelerator patients through the first three operating years of the project.

Project growth in brachytherapy utilization based on historical utilization - The applicant states that it calculated the average annual growth rate of 9.6 percent for brachytherapy utilization based on data from FY2017 to FY2020. However, the applicant assumes the future average annual growth of the hospital’s brachytherapy services will be one percent, based on projected Orange population growth, through the first three operating years of the proposed project.

Identify the brachytherapy patients that would be appropriate for MR simulation - The applicant states that, based on the clinical expertise of faculty and staff, it projected the percentage of brachytherapy patients that would benefit from MR simulation rather than CT simulation, and applied that percentage to the projected number of brachytherapy patients through the first three operating years of the project. The applicant states that each brachytherapy patient would receive an average of three MR simulations in the course of treatment.

In Section Q, Form C, page 4, the applicant provides a table showing the total projected MR simulator procedures through the first three operating years, as summarized below:

UNC Hospitals MR Simulator Projected Utilization			
	FY 1 FY2022	FY 2 FY2023	FY 3 FY 2024
Linear accelerator patients	2,111	2,227	2,350
Brachytherapy patients	174	176	178
Total Patients	2,285	2,404	2,528
MR simulation procedures for linear accelerator patients	441	465	491
MR simulation procedures for brachytherapy patients	497	502	507
Total MR Simulation Procedures	938	968	998

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on historical utilization of UNC Hospital’s radiation oncology services, the clinical expertise of the hospital’s faculty and staff regarding the percentage of patients that would be appropriate for MR simulation, and the projected population growth rate for the Orange County service area.
- The applicant provides reasonable and adequately supported information to justify the need for the MR simulator.

Access

In Section C.11, pages 44-45 the applicant states it will provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental condition, age, ability to pay, or any other factor. In Section L.3, page 79, the applicant projects the following payor mix for UNC Hospitals and radiation oncology services during the third year of operation (FY2024) following completion of the project, as shown in the following table.

Payment Source	Percent of Total for Entire Facility	Percent of Total for Radiation Oncology
Self Pay	8.8%	4.1%
Medicare	34.2%	48.2%
Medicaid	15.3%	9.5%
Insurance	37.0%	31.3%
Other*	4.8%	6.9%
Total**	100.0%	100.0%

Source: Table on page 79 of the application.

*The applicant states the “Other” category includes TRICARE, Workers Compensation and other government payors.

**Totals may not foot due to rounding.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose the reduction or elimination of a service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant proposes to acquire a MR simulator pursuant to Policy AC-3.

In Section E, pages 54-56, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the status quo: The applicant states this option is not an effective alternative because it would not permit the hospital to offer the optimal standard of care to radiation oncology patients, nor address the research and faculty recruitment and retention objectives of the proposed project.

Utilize existing fixed MRI scanner for simulations: The applicant states it considered the alternative of utilizing its existing fixed MRI scanner to perform the MR simulations but determined that the existing MRI scanners are designed for their diagnostic capabilities whereas the proposed MR simulator is designed specifically for radiation treatment planning.

Apply for a fixed MRI scanner when available through a need determination in the SMFP: The applicant states it considered this alternative, but determined that it had numerous disadvantages, including the uncertainty of when the need determination would arise and whether or not the hospital's MRI scanner application would ultimately be approved.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- The application is conforming to all statutory and regulatory criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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 no more than one MR simulator.**
- 3. University of North Carolina Hospitals at Chapel Hill, as part of this project, shall not acquire 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. For each of the first five years of operation, University of North Carolina Hospitals at Chapel Hill shall submit to the Healthcare Planning and Certificate of Need Section a detailed description of how the project achieves the academic requirements of the appropriate sections of Policy AC-3, paragraph 2 [items 1 through 4] as proposed in the certificate of need application.**

5. **University of North Carolina Hospitals at Chapel Hill shall report the Policy AC-3 MR simulator on the appropriate annual license renewal application for the asset. The information to be reported for the MR simulator shall include: (a) the number of approved units; (b) the annual volume of cases or procedures performed for the reporting year; and (c) the patient origin by county.**
 6. **If the MR simulator ceases to be used for clinical teaching or research, University of North Carolina Hospitals at Chapel Hill shall surrender the certificate of need.**
 7. **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.**
 8. **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 insurance 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 proposes to acquire a MR simulator pursuant to Policy AC-3.

Capital and Working Capital Costs

In Section Q, the applicant projects the total capital cost of the project as shown in the table below.

Construction/Renovation Costs	\$1,188,171
Architectural/Engineering Fees	\$179,000
Medical Equipment Costs	\$2,329,000
Furniture	\$10,000
Other Costs/Contingency	\$597,000
Total	\$4,303,171

In Section Q, Form F.1(a), the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 59, the applicant projects there will be no start-up costs or initial operating expenses associated with the proposed project is not a new service.

Availability of Funds

In Section F.2, page 57, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing		
Type	UNC Hospitals	Total
Loans	\$0	\$0
Accumulated reserves or OE *	4,303,171	\$4,303,171
Bonds	\$0	\$0
Other (Tenant Allowance)	\$0	\$0
Total Financing	\$4,303,171	\$4,303,171

* OE = Owner's Equity

In Exhibit F.2-1, the applicant provides a letter dated February 17, 2020, from the Chief Financial Officer for UNC Hospitals documenting its intention to provide accumulated reserves to finance the proposed project. Exhibit F.2-2 contains a copy of the audited financial statements for UNC Hospitals for the year ended June 30, 2019 which indicate that UNC Hospitals had \$241 million in cash and cash equivalents as of June 30, 2019. 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 Form F.3, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years of the project, as shown in the table below.

UNC Hospitals Radiation Oncology Revenue and Expenses			
	FY 1 (FY2022)	FY 2 (FY2023)	FY 3 (FY2024)
Total Gross Revenues (Charges)	\$178,062,680	\$192,892,565	\$208,984,700
Total Net Revenue	\$56,998,480	\$61,745,578	\$66,896,726
Total Operating Expenses (Costs)	\$37,052,397	\$39,777,443	\$42,490,806
Net Income / (Loss)	\$19,946,083	\$21,968,135	\$24,405,920

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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
 - 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.
- (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 a MR simulator pursuant to Policy AC-3. The proposed equipment will be located in renovated space on the hospital's main campus in Chapel Hill.

N.C.G.S. §131E-176(24a) states: "*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*" The 2020 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. Section 10A NCAC 14C .1901, Criteria and Standards for Radiation Therapy Equipment, subsection (13) states, "*'Radiation therapy service area' means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.*" In Chapter 17, Table 17C-4, page 408 of the 2020 SMFP, Orange County is included in Linear Accelerator Service Area 14, which also includes Chatham County. Providers may serve residents of counties not included in their service area.

In Section G.1, page 64, the applicant describes the service area as follows:

"The 2020 SMFP does not define service areas for simulators. Based on the proposed location of the equipment and the source of the largest percentage of patients expected to utilize the proposed equipment, UNC Hospitals has defined the service area as Orange County, though it expects to service patients from other areas as well. UNC Hospitals is the only existing provider of radiation oncology services in Orange County, which is the service area for the proposed project."

In Section G.3, page 64, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in the proposed service area. The applicant states:

“The proposed project will not result in any unnecessary duplication of existing or approved facilities that provide the same service component because UNC Hospitals is the only existing provider of radiation oncology services in Orange County, which is the service area for the proposed project.

Furthermore, according to the 2020 SMFP and Google Maps, there are no non-academic medical center teaching hospital providers within 20 miles that offer MR simulation-based radiation therapy treatment. In fact, according to the 2020 SMFP, only two providers in the state, Duke University Hospital and North Carolina Baptist Hospital, operate MRI scanners dedicated for radiation oncology. Duke University Hospital is within 20 miles of UNC Hospitals’ main campus but it is an academic medical center and the utilization of the MRI scanner dedicated for radiation oncology at Duke University Hospital is not reported; thus, it is difficult to discern the level of capacity available (or unavailable) at Duke University Hospital for MR simulation-based radiation therapy treatment. Moreover, it is not practical for patients being treated at UNC Hospitals to have MR simulation performed at another facility.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed MR simulator is needed and that there are no other existing MR simulators in the proposed service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 projected full-time equivalent (FTE) staffing for the proposed services as shown in the following table.

Projected Staffing (FTE)			
UNC Hospitals Radiation Oncology			
Position	FY1 (FY2022)	FY2 (FY2023)	FY3 (FY2024)
Registered Nurse	8.0	8.0	8.0
Aides/Orderlies	10.0	10.0	10.0
Administrator	0.3	0.3	0.3
Dosimetrist	7.0	7.0	7.0
Physicist	3.0	3.0	3.0
Radiation Therapy Technician	23.3	23.8	23.8
Total*	51.6	52.0	52.0

Source: Form H in Section Q of the application.

*Totals may not foot due to rounding

Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Sections H.2 and H.3, pages 66-67, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs. In Section I.3, page 69, the applicant identifies the physician that will serve as 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

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

C

In Section I.1, page 68, the applicant states UNC Hospitals currently provides all of the ancillary and support services necessary for the proposed MR simulator. The applicant states,

“As an existing full-service academic medical center, UNC Hospitals has all ancillary and support services in place to support hospital operations, including the existing radiation oncology services at its main campus. These existing ancillary and support services also will support the MR simulator proposed in this application. Patients may

require the use of any of UNC Hospitals' existing ancillary and support services including laboratory, radiology, pharmacy, dietary, housekeeping, maintenance, and administration, among others."

In Section I.1, page 68, and Exhibit I.1, the applicant adequately explains how each ancillary and support service will be made available. In Section I.2, page 68, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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 K.2, page 72, the applicant states the project involves renovating 1,069 square feet of existing space in the radiation oncology department of the hospital. Line drawings are provided in Exhibit C.1-3.

In Section K.3, page 72, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K.3, pages 72-73, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.3, page 73, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 77, the applicant provides the historical payor mix UNC Hospitals and radiation oncology services for the FY2019, as shown in the table below.

Payment Source	Percent of Total for Entire Facility	Percent of Total for Radiation Oncology
Self Pay	8.8%	4.1%
Medicare	34.2%	48.2%
Medicaid	15.3%	9.5%
Insurance	37.0%	31.3%
Other*	4.8%	6.9%
Total**	100.0%	100.0%

Source: Table on page 77 of the application.

*The applicant states the "Other" category includes TRICARE, Workers Compensation and other government payors.

**Totals may not foot due to rounding.

In Section L.1, page 76, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility during the Last Full FY2019	Percentage of the Population of the Service Area
Female	58.4%	52.2%
Male	41.6%	47.8%
Unknown	0.0%	0.0%
64 and Younger	74.2%	86.0%
65 and Older	25.8%	14.0%
American Indian	0.6%	0.6%
Asian	2.0%	8.3%
Black or African-American	22.4%	11.8%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	61.3%	76.6%
Other Race	9.5%	2.6%
Declined / Unavailable	4.1%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 77, 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 State Fiscal Year 2019 is estimated to be more than \$266 million. 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, pages 78-79, the applicant states that during the last five years, three patient civil rights access complaints have been filed against its facilities, including UNC Hospitals, UNC Rockingham Hospital, and Caldwell Memorial Hospital. The applicant states that the three complaints have been investigated and resolved.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 79, the applicant projects the following payor mix for UNC Hospitals and radiation oncology services during the third year of operation (FY2024) following completion of the project, as shown in the following table.

Payment Source	Percent of Total for Entire Facility	Percent of Total for Radiation Oncology
Self Pay	8.8%	4.1%
Medicare	34.2%	48.2%
Medicaid	15.3%	9.5%
Insurance	37.0%	31.3%
Other*	4.8%	6.9%
Total**	100.0%	100.0%

Source: Table on page 79 of the application.

*The applicant states the "Other" category includes TRICARE, Workers Compensation and other government payors.

**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 4.1 percent of total radiation oncology services will be provided to self-pay patients, 48.2 percent to Medicare patients, and 9.5 percent to Medicaid patients.

In Section Q, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L.5, page 80, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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, pages 81-82, the applicant describes the extent to which health professional training programs in the area have access to the proposed health services for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, 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

UNC Hospitals proposes to acquire a MR simulator pursuant to Policy AC-3. The proposed equipment will be located in renovated space on the hospital's main campus in Chapel Hill.

N.C.G.S. §131E-176(24a) states: “*Service area means the area of the State, as defined in the State Medical Facilities Plan or rules adopted by the Department, which receives services from a health service facility.*” The 2020 SMFP does not define a service area for simulators, nor are there any applicable rules adopted by the Department that define the service area for simulators. Section 10A NCAC 14C .1901, Criteria and Standards for Radiation Therapy Equipment, subsection (13) states, “*‘Radiation therapy service area’ means a single or multi-county area as used in the development of the need determination in the applicable State Medical Facilities Plan.*” In Chapter 17, Table 17C-4, page 408 of the 2020 SMFP, Orange County is included in Linear Accelerator Service Area 14, which also includes Chatham County. Providers may serve residents of counties not included in their service area.

In Section N.1, page 84, the applicant describes the expected effects of the proposed services on competition in the service area and 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 believes that the proposed project will foster competition in the proposed service area, particularly as the proposed project will make UNC Hospitals only the third provider in North Carolina to offer radiation therapy treatment planning with the use of an MR simulator. According to the 2020 SMFP, only two other providers in the state, Duke University Hospital and North Carolina Baptist Hospital, operate MRI scanners dedicated for radiation oncology. Moreover, UNC Hospitals, has a unique mission to serve patients from across the state, and regularly cares for patients from all 100 counties. As such, the proposed project will enhance competition by improving the radiation oncology services at UNC Hospitals, which will improve its ability to compete with other providers, nationwide. The proposed project will assist UNC Hospitals in meeting its four-fold mission of patient care, teaching, research, and community service.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits).
- Quality services will be provided (see Section O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections C, D, and L of the application and any exhibits).

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 Q, Form A, the applicant identifies 13 health care facilities owned or managed by UNC Health Care System.

In Section O.3, page 88, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred at one UNC Health Care System facility, UNC REX Hospital. In Section O.3, page 88, the applicant states that a plan of correction for UNC REX Hospital was accepted and the hospital is back in compliance with all CMS conditions as of July 19, 2019. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the UNC Health Care System facilities are back in compliance with all CMS Conditions of Participation. 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 UNC Health Care System facilities, the applicant provides 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 applicant proposes to acquire a MR simulator pursuant to Policy AC-3. The Criteria and Standards for Radiation Therapy Equipment, NCAC 14C .1900, are applicable.

SECTION .1900 – CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT

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 does not propose 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 does not propose 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

-NA- The applicant states the proposed MR simulator will not perform patient treatments.

(2) the maximum number and type of procedures that the proposed equipment is capable of performing.

-C- The applicant states the proposed MR simulator will have the capacity for a maximum of 10 patients per day of operation and that the equipment will be operational approximately 250 days per year for a maximum annual capacity of 2,500 patients, annually.

(d) The applicant shall document all assumptions and provide data supporting the methodology used to determine projected utilization as required in this Rule.

-NA- The applicant does not propose to acquire a linear accelerator.