

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2023

Findings Date: October 4, 2023

Project Analyst: Julie M. Faenza

Co-signer: Micheala Mitchell

COMPETITIVE REVIEW

Project ID #: J-12371-23
Facility: UNC Rex Hospital
FID #: 953429
County: Wake
Applicant: Rex Hospital, Inc.
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #: J-12376-23
Facility: WakeMed Raleigh Medical Park
FID #: 090441
County: Wake
Applicant: WakeMed
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #: J-12379-23
Facility: Duke Radiation Oncology Garner
FID #: 230343
County: Wake
Applicant: Duke University Health System, Inc.
Project: Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (Agency) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

Given the complexity of this review and the multiple entities involved in projections, the Project Analyst created the table below listing acronyms or abbreviations used in the findings.

Acronyms/Abbreviations Used	
Acronym/Abbreviations Used	Full Term
ESTV	Equivalent Simple Treatment Visits
LINAC	Linear Accelerator
SBRT	Stereotactic Body Radiation Therapy
SRS	Stereotactic Radiosurgery

CAGR	Compound Annual Growth Rate
FFY	Federal Fiscal Year (October 1 – September 30)
FY	Fiscal Year
NC OSBM	North Carolina Office of State Budget and Management
SFY	State Fiscal Year (July 1 – June 30)
SHCC	State Health Coordinating Council
SMFP	State Medical Facilities Plan

DUHS	Duke University Health System, Inc.
Duke Cary	Duke Cancer Center Cary Radiation Oncology
Duke Garner	Duke Radiation Oncology Garner
Duke Green Level	Duke Cancer Center Green Level Radiation Oncology
Duke Women’s Cancer	Duke Women’s Cancer Care Raleigh
UNC-CH	University of North Carolina Hospitals at Chapel Hill
UNC Panther Creek	UNC Health Cancer Care of Panther Creek
UNC Rex East Raleigh	UNC Health Rex Cancer Care of East Raleigh
UNC Rex Wakefield	UNC Health Rex Cancer Care of Wakefield
UNC System	University of North Carolina Health Care System
WakeMed RMP	WakeMed Raleigh Medical Park

REVIEW CRITERIA

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

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

NC – UNC Rex Hospital, Duke Radiation Oncology Garner C – WakeMed Raleigh Medical Park

Need Determination – Chapter 17 of the 2023 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional LINAC equipment in North Carolina by service area. Application of the need methodology in the 2023 SMFP did not result in a need determination for any LINACs in any service area in North Carolina. However, pursuant to a petition filed with the State Health Coordinating Council (SHCC), the SHCC approved an adjusted need determination for one LINAC in Service Area 20. Service Area 20 is comprised of Franklin and Wake counties.

Policies – There are two policies in the 2023 SMFP which are applicable to this review.

Policy GEN-3: Basic Principles, on page 30 of the 2023 SMFP, states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 30 of the 2023 SMFP, states:

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

Both policies apply to all applications.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

Rex Hospital, Inc. (hereinafter referred to as "Rex," "UNC Health," or "the applicant") proposes to add a second fixed linear accelerator (LINAC) at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield), a campus of UNC Health Rex Hospital (UNC Rex Hospital).

Rex Hospital, Inc. is a North Carolina nonprofit corporation whose sole member is Rex Healthcare, Inc. Rex Healthcare, Inc. is a North Carolina nonprofit corporation whose sole member is the University of North Carolina Health Care System (UNC System). On its 2023 Hospital License Renewal Application, Rex identifies itself as being part of the UNC System.

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, pages 26-32, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to acquire a new LINAC and does not adequately demonstrate that acquiring a new LINAC would not be an unnecessary duplication of existing and approved services. The discussions regarding need (and projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project, does not demonstrate that projected utilization is reasonable and adequately supported, and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Thus, the application is not consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than \$5 million. In Section B, page 33, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to acquire a new LINAC or that acquiring a new LINAC would not be an unnecessary duplication of existing and approved health care services.
- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

WakeMed (hereinafter referred to as “WakeMed” or “the applicant”) proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed’s main campus (WakeMed Raleigh Campus).

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, pages 29-35, the applicant explains why it believes its proposal is consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than \$5 million. In Section B, pages 36-38, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to develop more LINACs than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 based on the following:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of LINAC services in Service Area 20.
 - The applicant adequately documents how the project will promote equitable access to LINAC services in Service Area 20.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

Duke University Hospital System, Inc. (hereinafter referred to as “Duke,” “DUHS,” or “the applicant”) proposes to acquire a LINAC and CT simulator and develop a new radiation oncology facility, Duke Radiation Oncology Garner (Duke Garner). The facility will be licensed under Duke Raleigh Hospital.

Need Determination. The applicant does not propose to acquire more LINACs than are determined to be needed in Service Area 20 and proposes to develop the LINAC in Wake County. Therefore, the application is consistent with the need determination.

Policy GEN-3. In Section B, page 28, the applicant explains why it believes its proposal is consistent with Policy GEN-3. The applicant cites to Sections M, N, and O on pages 83-88 where it discusses how the proposed project will promote safety, quality, and ensure equitable access to care as well as maximize healthcare value for the resources expended.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to acquire a new LINAC and does not adequately demonstrate that acquiring a new LINAC would not be an unnecessary duplication of existing and approved services. The discussions regarding need (and projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project,

does not demonstrate that projected utilization is reasonable and adequately supported, and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. Thus, the application is not consistent with Policy GEN-3.

Policy GEN-4. The capital expenditure of the project is greater than \$5 million. In Section B, pages 28-29, the applicant describes its plan to assure improved energy efficiency and water conservation.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on the following:

- The applicant does not adequately demonstrate the need to acquire a new LINAC or that acquiring a new LINAC would not be an unnecessary duplication of existing and approved health care services.
- Therefore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum healthcare value for resources expended as required in Policy GEN-3.

(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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park**

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield)

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties.

Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

Current & Projected Patient Origin – UNC Rex Wakefield – Radiation Therapy								
	Current – SFY* 2022		FY 1 – SFY* 2026		FY 2 – SFY* 2027		FY 3 – SFY* 2028	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	471	70.9%	528	71.4%	537	71.5%	548	71.5%
Franklin	151	22.7%	169	22.9%	172	22.9%	176	22.9%
Vance	11	1.7%	11	1.5%	11	1.5%	11	1.5%
Other**	31	4.7%	31	4.2%	31	4.2%	31	4.2%
Total	664	100.0%	740	100.0%	752	100.0%	766	100.0%

Source: Section C, pages 39-40

Note: Table may not foot due to rounding.

*SFY – State Fiscal Year (July 1 – June 30)

**Other: Other counties in North Carolina as well as other states

In Section C, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions and methodology used to project patient origin are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on historical patient origin.
- The applicant adjusts the projected patient origin based on projected changes in utilization that impact the patient origin.

Analysis of Need – In Section C, pages 42-63, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- There is an adjusted need determination for one LINAC in Service Area 20. The applicant states that, at the time of the petition requesting the adjusted need determination, the applicant was opposed to the petition; however, the applicant states its situation has changed between when the petition was filed and the submission of the application. The applicant states its annualized LINAC utilization has increased by 9.3% over State Fiscal Year (SFY) 2022 and increased by 4.2% over its SFY 2019 volume. (pages 42-44)
- Developing a second LINAC at the UNC Rex Wakefield campus will allow the applicant to provide stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) services at that location, which are not currently offered there. (pages 44-45)
- The applicant states that, according to the NC Office of State Budget and Management (NC OSBM), the Wake County total population grew by 22.3% between 2013 and 2023, and over the last 10 years Wake County added more residents than the combined 2023 total population of 88 of North Carolina’s 100 counties. The applicant states the Franklin County total population increased by even more – 22.8% – during the same time period. The

applicant states that NC OSBM data shows the population in Service Area 20 grew at twice the rate of the overall statewide population growth. The applicant also states NC OSBM projects Service Area 20 will grow at a compound annual growth rate (CAGR) of 2.1% between 2023 and 2028, while the total statewide population growth rate is projected to be 1.1% between 2023 and 2028. (pages 45-46)

- The applicant states the population in Service Area 20 is aging at a more rapid rate than the state as a whole. The applicant states that, according to NC OSBM, the Service Area 20 population age 65 and older grew at a CAGR of 5.5% between 2013 and 2023, compared with 3.3% for the total statewide population age 65 and older. The applicant states NC OSBM projects Service Area 20's population age 65 and older will grow at a 5% CAGR between 2023 and 2028, compared with the total statewide population age 65 and older, which is projected to grow at a 2.8% CAGR between 2023 and 2028. The applicant states people aged 65 and older are eleven times more likely to develop cancer than younger patients. (pages 46-47)
- The applicant states Franklin County has been without a LINAC since 2019 and that there are health, socioeconomic, and other disparities that necessitate putting the LINAC at UNC Rex Wakefield. (pages 47-52)
- The applicant's LINACs in Service Area 20 were the highest utilized out of all LINACs in Service Area 20 in the three most recent historical periods for which data is available. (pages 52-57)
- The LINAC at UNC Rex Wakefield is the highest utilized LINAC in all of Service Area 20. Because of additional services available on the campus, and because of the need to provide SRT and SBRT services to Franklin County residents, the LINAC is needed specifically at UNC Rex Wakefield. (pages 57-63)

However, the information is not reasonable and adequately supported based on the following reasons:

- The applicant is part of the UNC System. The UNC System is also the parent company of University of North Carolina Hospitals at Chapel Hill (UNC-CH), which holds a certificate of need to develop a LINAC in Service Area 20 that is more than seven years old, and which does not appear to be under development.

UNC-CH applied to acquire a new LINAC, to be located at its hospital campus in Holly Springs, as part of the 2014 Service Area 20 LINAC review. A decision was issued in that competitive review on January 28, 2015 and was appealed. As the result of a settlement agreement, a certificate of need was issued to UNC-CH on April 29, 2016. Progress reports submitted by UNC-CH subsequent to the issuance of the certificate of need through the end of 2019 stated that the LINAC was to be located on the UNC Rex Holly Springs hospital campus under development and therefore could not be fully developed until the hospital campus itself was fully developed.

On September 8, 2020, UNC-CH submitted a material compliance request to relocate the approved but not yet developed LINAC to the UNC Panther Creek campus in Morrisville, roughly 16 miles north of the location approved in the certificate of need. The Agency issued a determination that the proposed relocation was materially compliant with the certificate of need on September 16, 2020.

The subsequent progress reports submitted by UNC-CH to the Agency on February 1, 2021, July 1, 2021, and November 1, 2021 stated that because of the impact of the COVID-19 pandemic on healthcare, there was a delay in developing the campus. The progress report submitted on November 1, 2021 stated that development was anticipated to begin again in early 2022.

In a progress report submitted to the Agency on March 1, 2022, UNC-CH stated that the proposed project was now part of a system-wide review process and anticipated development would begin upon completion of that review process. UNC-CH did not provide any timetable upon which the development would begin again and has not submitted another progress report to the Agency in the 18 months since.

- On May 30, 2023 – after the beginning of this review – UNC-CH submitted a material compliance requesting a transfer for good cause. UNC-CH proposed to transfer ownership to the applicant and noted that it was an intraorganizational transfer due to the shared parent company. The letter also stated that the material compliance request submitted on September 8, 2020 would be withdrawn and the applicant would develop the LINAC at the location originally approved in the certificate of need. The Agency approved the transfer for good cause on June 6, 2023. No timetable for development was provided in the letter requesting the transfer for good cause.
- In Section C, page 43, the applicant states that its comments in opposition to WakeMed’s petition for an adjusted need determination “...were also reflective of volume trends at the time of submission, which indicated flat to negative growth in LINAC utilization at UNC Rex Health facilities.” The applicant was able to provide care to its existing LINAC patients during the last seven and a half years without taking further steps to develop the approved LINAC. The applicant does not explain how its utilization increase over the last eight months shows a need for an additional LINAC when it has not yet developed the LINAC it was approved to develop nearly seven and a half years ago.

Projected Utilization – On Forms C.2a and C.2b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following table.

UNC Rex Wakefield LINAC – Historical and Projected Utilization				
	Historical SFY 2022	FY 1 SFY 2026	FY 2 SFY 2027	FY 3 SFY 2028
# of Units	1	2	2	2
# of ESTV Treatments*	6,768	7,538	7,662	7,804
# of Patients	664	740	752	766

*ESTV = Equivalent Simple Treatment Visits

In the Form C Utilization – Methodology and Assumptions subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant’s LINAC utilization at UNC Rex Wakefield increased at a CAGR of 0.1% between SFY 2019 and SFY 2023 annualized. The applicant states the lack of growth is due to the high capacity of patients treated at UNC Rex Wakefield.
- The applicant begins projections with SFY 2023 annualized utilization and assumes that utilization will increase at an annual rate of 0.1% through the end of the third full fiscal year following project completion.
- The applicant projects growth in the patient population receiving SRT and SBRT services at UNC Rex Hospital and that live in northern Wake County and Franklin County will grow at an annual rate of 16.4%, consistent with the SFY 2019 through SFY 2023 CAGR for those patients. The applicant then assumes 90% of those patients will shift care to UNC Rex Wakefield once the second LINAC is operational.

The applicant’s assumptions and methodology are summarized in the table below.

UNC Rex Wakefield LINAC – Historical and Projected Utilization						
	Interim			Projected		
	SFY 2023	SFY 2024	SFY 2025	FY 1 SFY 2026	FY 2 SFY 2027	FY 3 SFY 2028
# of Units	1	1	1	2	2	2
# of Patients (0.1% growth)	668	668	669	669	670	671
# of SRT/SBRT Patients (16.4% growth)	50	58	67	78	91	106
# of SRT/SBRT Patients Shifting (90%)	--	--	--	70	82	95
Total # of Patients	668	668	669	740	752	766
Average # of Patients per LINAC	668	668	669	370	376	383

UNC Health System – Service Area 20 – Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all UNC LINACs in Service Area 20, which are summarized below.

- The applicant has a total of six existing and approved LINACs. There are three existing LINACs at UNC Rex Hospital. There is one existing LINAC at UNC Rex Wakefield and one existing LINAC at UNC Rex East Raleigh. There is an approved but not yet developed LINAC that will be located at UNC Panther Creek in Cary.
- The applicant analyzed the number of patients it had served each year at UNC Rex Hospital and at UNC Rex East Raleigh between SFY 2019 and SFY 2023 annualized. The applicant

determined patient utilization had increased at a CAGR of 3.3% between SFY 2019 and SFY 2023 annualized at UNC Rex Hospital and patient utilization had decreased at a CAGR of -5.9% between SFY 2019 and SFY 2023 annualized at UNC Rex East Raleigh.

- The applicant begins its utilization projections with SFY 2023 annualized utilization at each facility.
- The applicant projected growth in patient utilization at UNC Rex Hospital through the third full fiscal year following project completion at an annual rate of 3.3%, consistent with its historical CAGR between SFY 2019 and SFY 2023 annualized.
- The applicant projected patients from northern Wake County and Franklin County that had historically received SRT and SBRT at UNC Rex Hospital would grow at an annual rate of 16.4% through the third full fiscal year following project completion, consistent with the applicant’s SFY 2019 through SFY 2023 annualized CAGR for those patients. The applicant projected 90% of the SRT and SBRT patients who live in northern Wake County and Franklin County will shift to UNC Rex Wakefield once the second LINAC is operational.
- The applicant projected patients from southwest Wake County that had historically utilized the LINACs at UNC Rex Hospital would grow at an annual rate of 6.1% through the third full fiscal year following project completion, consistent with the applicant’s SFY 2019 through SFY 2023 annualized CAGR for those patients. The applicant projected 50% of the patients who live in southwest Wake County will shift to UNC Panther Creek once the approved LINAC is developed.
- The applicant states patient utilization at UNC Rex East Raleigh was relatively steady between SFY 2019 and SFY 2022 before a decline in SYF 2023 annualized. The applicant states it has taken steps to stabilize scheduling and expects utilization to increase as there are capacity constraints elsewhere. The applicant states that it projects no growth in the utilization rate at UNC Rex East Raleigh through the third full fiscal year following project completion.

The applicant’s assumptions and methodology are summarized in the table below.

UNC Rex Health System LINAC Utilization – Service Area 20									
Facility	Patients						# LINACs	Patients/LINAC	
	SFY 2023*	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028			
UNC Rex Hospital (3.3%)	1,748	1,806	1,866	1,929	1,993	2,060			
Patient Shift to UNC Rex Wakefield	--	--	--	-70	-82	-95			
Patient Shift to UNC Panther Creek	--	--	--	-380	-404	-429			
UNC Rex Hospital Patients	1,748	1,806	1,866	1,478	1,508	1,536	3	512	
UNC Rex Wakefield (0.1%, w/shifts)	668	668	669	740	752	766	2	383	
UNC Rex East Raleigh (0.0%)	386	386	386	386	386	386	1	386	
UNC Panther Creek (all shifts)	--	--	--	380	404	429	1	429	
Total	2,802	2,860	2,921	2,984	3,050	3,117	7	445	

*Annualized

As shown in the table above, each individual LINAC as well as the average utilization across all LINACs owned and operated by UNC Rex in Service Area 20 are projected to exceed 250 patients per LINAC during the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

However, projected utilization is not reasonable and adequately supported based on the following reasons:

- The UNC System and its subsidiaries have not yet developed the LINAC approved to develop nearly seven and a half years ago and has not provided any update to the Agency about when the LINAC will be developed. Please see the discussion above Analysis of Need. The history with regard to development of the approved LINAC calls into question the utilization projections from the applicant.
- The applicant does not adequately explain why it relied on historical utilization data that has an outlier year which significantly changes utilization projections.

The applicant projects growth in utilization of potential SRS and SBRT patients from northern Wake County and Franklin County based on its SFY 2023 annualized data and using the CAGR for utilization between SFY 2019 and 2023 annualized. However, historical utilization for SRS and SBRT patients from northern Wake County and Franklin County was flat between SFY 2019 and SFY 2022 before doubling between SFY 2022 and 2023 annualized. The inclusion of this outlier year skews the CAGR significantly higher than historical utilization trends reflect. Further, the applicant applied the skewed CAGR to the outlier year with double the historical utilization to project future utilization.

In its responses to comments, the applicant states that the utilization trend between SFY 2019 and 2023 annualized is consistent with overall growth in utilization after a decline due to the impact of the COVID-19 pandemic. However, that is not consistent with the information provided by the applicant about historical utilization.

The table below shows all historical utilization data sets provided by the applicant in Section Q.

Historical Utilization Data Sets in Section Q					
	SFY 2019	SFY 2020	SFY 2021	SFY 2022	SFY 2023*
UNC Rex Hospital Patients (p.1)	1,532	1,670	1,458	1,424	1,748
UNC Rex Wakefield Patients (p.1)	665	708	682	664	668
UNC Rex East Raleigh Patients (p.1)	491	497	475	474	386
Average Patients per LINAC (p.1)	538	575	523	512	560
Potential Patients from Holly Springs/Panther Creek (p.3)	501	653	563	490	636
Potential SRS/SBRT Patients from N Wake/Franklin (p.3)	27	24	24	25	50

*Annualized

In all other sets of historical utilization provided by the applicant, utilization increased between SFY 2019 and 2020, then declined (presumably due to the impact of COVID-19) between SFY 2020 and 2022, before increasing again in SFY 2023 annualized. In some

cases, utilization in SFY 2023 annualized was higher than it had been in SFY 2020; in other cases, utilization in SFY 2023 annualized increased noticeably over SFY 2022 but did not eclipse utilization in SFY 2020. However, in no other data set did utilization decline or remain flat between SFY 2019 and SFY 2020, and in no other data set did utilization remain flat between SFY 2020 and 2022 before doubling between SFY 2022 and SFY 2023 annualized.

Further, the data set for UNC Rex East Raleigh is also an outlier. Instead of following the historical utilization trends for the other data sets listed above, utilization for UNC Rex East Raleigh noticeably declined between SFY 2022 and SFY 2023 annualized. However, the applicant treated this outlier differently. The applicant did not rely on what would be a negative SFY 2019 through 2023 annualized CAGR to project utilization at UNC Rex East Raleigh; instead, it projected no growth in utilization.

The applicant provides no information in the application as submitted to explain why it is reasonable to include an outlier year which results in a significantly higher CAGR and increased utilization over historical trends while not including an outlier year which would result in a negative CAGR and decreased utilization over historical trends.

- On May 30, 2023 – after the beginning of this review – UNC-CH submitted a material compliance requesting a transfer for good cause. UNC-CH proposed to transfer ownership to the applicant and noted that it was an intraorganizational transfer due to the shared parent company (UNC System). The letter also stated that the material compliance request submitted on September 8, 2020 would be withdrawn and the applicant would develop the LINAC at the location originally approved in the certificate of need. The Agency approved the transfer for good cause on June 6, 2023. No timetable for development was provided in the letter requesting the transfer for good cause.

Utilization projections in this application assume the approved LINAC will be developed at the UNC Panther Creek campus. The location where the LINAC will be developed is approximately 16 miles further south into Wake County. Because the LINAC will not be developed where the utilization projections assume the LINAC will be developed, that further calls into question the reasonableness of the utilization projections made by the applicant.

Access to Medically Underserved Groups – In Section C, page 70, the applicant states:

“..., UNC Health Rex prohibits the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability, or the patient’s ability to pay. In particular, as stated in UNC Health Rex’s Patient Rights and Responsibilities Policy, patients have the right to receive “care that is free of discrimination” and “medically necessary treatment regardless of [their] ability to pay.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Racial and ethnic minorities	26.3%
Women	60.2%
Persons 65 and older	57.0%
Medicare beneficiaries	59.3%
Medicaid recipients	1.3%

Source: Section C, page 74

On page 75, the applicant states it does not maintain data on the number of low-income or disabled people it serves but that neither low-income nor disabled people are denied access to services.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups, without regard for anything other than the need for LINAC services.
- The applicant provides documentation of its existing policies regarding non-discrimination in Exhibit B.20-3 and its financial policies in Exhibit B.20-4.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

WakeMed RMP is not an existing facility and thus does not have historical patient origin. The table below shows projected patient origin.

Projected Patient Origin – WakeMed RMP – LINAC/Simulator						
	FY 1 – FFY* 2025		FY 2 – FFY* 2026		FY 3 – FFY* 2027	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Wake	189	74.0%	253	74.0%	327	74.0%
Franklin	10	3.9%	13	3.9%	17	3.9%
Harnett	19	7.6%	26	7.6%	34	7.6%
Johnston	11	4.2%	15	4.2%	19	4.2%
Other NC Counties	24	9.3%	32	9.3%	41	9.3%
Other States	3	1.0%	3	1.0%	4	1.0%
Total	255	100.0%	342	100.0%	442	100.0%

Source: Section C, page 51

*FFY = Federal Fiscal Year (October 1 – September 30)

In Section C, page 50, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions and methodology used to project patient origin are reasonable and adequately supported based on the following:

- The applicant considered the distribution of other LINACs in Wake and Durham counties in projecting utilization.
- The applicant relied on its Tumor Registry in projecting patient origin.

Analysis of Need – In Section C, pages 54-66, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The applicant has offered oncology services for many years but had to refer patients needing radiation therapy to other providers in the area because it lacks a LINAC. The applicant states analysis of data from its Tumor Registry and other acquired data shows its patients wait longer than the average for insured patients in Wake County from diagnosis to radiation therapy. The applicant states that it serves a significant number of medically underserved and indigent patients, and that while the WakeMed Raleigh campus may be accessible for those patients, other providers don’t necessarily have the same kind of access available for those medically underserved and indigent patients. (pages 54-56)
- Radiation therapy has become a standard modality in cancer care and treatment. The applicant needs a LINAC to be able to provide the standard modality in its cancer care program. (page 56)
- The applicant states that, in both 2021 and 2022, it referred out more patients for radiation therapy than it would need to meet the applicable performance standard for LINACs. (page 57)
- The applicant states its patients originate primarily from Franklin, Harnett, Johnston, and Wake counties. The applicant states that construction projects designed to connect highways and ease traffic will make the WakeMed Raleigh Campus more accessible for residents in Harnett and Johnston counties. Additionally, data from NC OSBM projects

population growth in Service Area 20 at an annual rate of 2.1% between 2023 and 2028 and population growth in the four counties that patients primarily originate from will increase by 2.0% between 2023 and 2028. Further, the population aged 45 and older, which account for 9 out of 10 cancer diagnoses, is projected to grow faster than the overall population projected growth in the four counties where patients primarily originate from. (pages 57-61)

- The applicant states the North Carolina Center for Health Statistics, Central Cancer Registry projected there would be 8,776 new cancer cases during 2022 in the four counties that patients primarily originate from. The applicant states that new cancer case rates increased in each of the four counties patients primarily originate from. (pages 61-62)
- The applicant states its Tumor Registry data shows that WakeMed radiation therapy patients between 2018 and 2022 waited an average of nearly 99 days for radiation therapy services, compared with the average of 27 days for Wake County commercially insured patients. The applicant states its own internal data shows patients with commercial insurance had the shortest wait times from referral to appointment, and patients with managed care, uninsured patients, and low-income underinsured patients had the longest waits. The applicant states that, as a Disproportionate Share Hospital (a designation from the Centers for Medicare and Medicaid Services for safety-net hospitals), it serves a significant amount of patients from minority and historically underserved groups and needs access to a LINAC. (pages 62-64)
- The applicant states that care fragmentation – when a patient has to visit different systems to receive services – increases the time from diagnosis to treatment and cites studies showing care fragmentation results in increased time to treatment, increased costs, and reduction in survival compared with care delivered by a single system. The applicant states that the difficulties can be compounded for patients who have difficulties with transportation access. (pages 64-65)
- The applicant states there are 11 existing and approved LINACs in the 2023 SMFP inventory for Service Area 20, but that only 9 of them are operational and two are not in service. The applicant states there is a third LINAC that was approved to be developed in Harnett County (Service Area 21) which was approved in 2015 but there is no indication of when it will be operational. The applicant states all other LINACs are each serving more than 250 patients per LINAC, and that projected growth in patient population will result in greater demand than the three approved but not yet developed LINACs will be able to handle. (pages 65-66)

The information is reasonable and adequately supported based on the following reasons:

- As a Disproportionate Share Hospital, WakeMed serves more medically underserved patients than hospitals without that designation.
- WakeMed's data shows that patients it refers elsewhere for treatment must wait longer than average for access to radiation therapy services.

- WakeMed is already referring more than 250 patients per year to other systems for LINAC services.
- The adjusted need determination for the additional LINAC in Service Area 20 was approved by the SHCC because the SHCC believes radiation therapy is now the standard of care for cancer programs.

Projected Utilization – On Form C.2b in Section Q, the applicant provides projected utilization, as illustrated in the following table.

WakeMed RMP – Projected Utilization – LINAC/Simulator			
	FY 1 FY 2026	FY 2 FY 2027	FY 3 FY 2028
# of Units	1	1	1
# of ESTV Treatments*	4,070	5,459	7,054
# of Patients	255	342	442

*ESTV = Equivalent Simple Treatment Visits

In the WakeMed Need and Utilization Methodology for Section C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant assumes that its area of patient origin will encompass Franklin, Harnett, Johnston, and Wake counties, because nearly 86% of WakeMed’s medical oncology patients originated from those four counties between August 2022 and March 2023. The applicant states approximately 2.9% of patients originated from Durham County, but because Durham County will soon have two LINACs developed close to its border in western Wake County, the applicant assumes the area of patient origin will not include Durham County and adjusted the project patient origin to account for the removal of Durham County patients. The applicant assumes that patient origin will be constant during the first three full fiscal years of operation.
- The applicant assumes that medical oncology patient patterns provide a reasonable baseline for projecting the need for radiation therapy patients. The applicant states the WakeMed Tumor Registry has a lag in data entry so not all FY 2022 patients are represented in the Tumor Registry (as of the submission of this application).
- The applicant projected population growth in the four counties using data from NC OSBM. The applicant states projections from NC OSBM are in calendar years, not fiscal years, but assumes any difference will not meaningfully impact projections.
- The applicant reviewed historical rates of new cancer cases per 1,000 population by county and by year using data from the North Carolina State Center for Health Statistics. The applicant then plotted the historical rates for each county and used Microsoft Excel’s graph trend function to calculate linear trends for the historical rates of new cancer cases that could be used in projecting future rates of new cancer cases. The applicant states that because each county has unique demographic and population trends, it is more accurate to

calculate rates individually by county rather than an aggregated rate. The applicant also notes that the historical rates of new cancer cases are based on reported diagnoses, and the historical data includes years where COVID kept many people from doing routine cancer screenings (and so the actual rates may be higher than the projected rates).

- The applicant projected the number of new cancer cases by county through the third full fiscal year of operation by applying the projected rates of new cancer cases (described above) to the projected population of each county.
- The applicant states data shows up to 60% of cancer patients will receive radiation therapy treatment and assumes, based on data from a different source, that 52.3% of new cancer patients will need radiation oncology. The applicant applied that assumption to the projected number of new cancer patients to estimate how many would need radiation therapy. The applicant also assumed there would be a recurrence rate requiring retreatment of approximately 23% and calculated the number of patients requiring more than one course of radiation therapy. The applicant then combined the number of patients needing radiation therapy and the patients requiring a second course of radiation therapy.
- The applicant assumed patients who had been treated by other providers would continue to be treated by other providers, and projected growth in the number of patients treated by other providers at the same growth rate NC OSBM projects for each county.
- The applicant subtracted the projected number of patients to be served by existing providers from the total projected number of new cancer cases that would need radiation therapy to obtain the number of unserved radiation therapy patients. The applicant assumed it would serve an increasing percentage of unserved radiation therapy patients originating from Franklin, Harnett, Johnston, and Wake counties during the first, second, and third full fiscal years of operation (21%, 23%, and 25%, respectively).
- The applicant assumed that approximately 10.32% of its patients would originate from outside of the four-county area of patient origin. The applicant multiplied the projected number of unserved patients it would serve by 10.32% to obtain the number of patients that would originate from outside of the four-county area of patient origin.
- The applicant states it referred 385 patients for treatment outside of WakeMed in FY 2022. The applicant states it will retain an increasing percentage of patients it historically referred elsewhere for treatment in the first, second, and third full fiscal years of operation (33%, 44%, and 55%, respectively) and adds those patients to the total.

The applicant's assumptions and methodology are summarized in the tables below.

WakeMed RMP Projected Utilization – Wake County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.082% CAGR)	1,204,356	1,230,400	1,256,524	1,282,697	1,308,878	1,335,058
New Cancer Cases (based on county linear trend)	6,521	6,811	7,108	7,411	7,721	8,037
New Radiation Oncology Cases (52.3%)	3,410	3,562	3,717	3,876	4,038	4,203
Retreated Cases (23% of New Cases above)	784	819	855	891	929	967
Total Cases	4,195	4,381	4,572	4,768	4,967	5,170
Radiation Oncology Cases at Other Providers (2.082%)	4,146	4,233	4,321	4,411	4,503	4,596
Unserviced Radiation Oncology Cases	48	149	252	357	464	574

WakeMed RMP Projected Utilization – Franklin County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.148% CAGR)	73,668	75,332	76,971	78,625	80,278	81,928
New Cancer Cases (based on county linear trend)	493	509	524	540	556	572
New Radiation Oncology Cases (52.3%)	258	266	274	282	291	299
Retreated Cases (23% of New Cases above)	59	61	63	65	67	69
Total Cases	317	327	337	347	358	368
Radiation Oncology Cases at Other Providers (2.148%)	278	284	290	296	302	309
Unserviced Radiation Oncology Cases	40	44	48	52	56	59

WakeMed RMP Projected Utilization – Harnett County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (1.584% CAGR)	137,811	139,774	142,008	144,340	146,736	149,076
New Cancer Cases (based on county linear trend)	748	769	793	818	843	868
New Radiation Oncology Cases (52.3%)	391	402	415	428	441	454
Retreated Cases (23% of New Cases above)	90	93	95	98	101	104
Total Cases	481	495	510	526	542	558
Radiation Oncology Cases at Other Providers (1.584%)	415	421	428	435	442	449
Unserviced Radiation Oncology Cases	66	74	82	91	100	110

WakeMed RMP Projected Utilization – Johnston County						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Population (2.087% CAGR)	235,925	241,433	246,695	251,779	256,733	261,592
New Cancer Cases (based on county linear trend)	1,345	1,402	1,458	1,515	1,572	1,629
New Radiation Oncology Cases (52.3%)	703	733	763	792	822	852
Retreated Cases (23% of New Cases above)	162	169	175	182	189	196
Total Cases	865	902	938	974	1,011	1,048
Radiation Oncology Cases at Other Providers (2.087%)	870	888	907	926	945	965
Unserviced Radiation Oncology Cases	--	13	31	49	66	83

WakeMed RMP Projected Utilization – Total Unserviced Cases in Area of Patient Origin						
	Interim			Projected		
	FFY 2023	FFY 2024	FFY 2025	FY 1 FFY 2026	FY 2 FFY 2027	FY 3 FFY 2028
Wake County	48	149	252	357	464	574
Franklin County	40	44	48	52	56	59
Harnett County	66	74	82	91	100	110
Johnston County	--	13	31	49	66	83
Total	154	279	412	548	686	826

WakeMed RMP Projected Utilization		
Unserviced Patients Projected to be Served		
FY 1 (FFY 2026) – 21%	FY 2 (FFY 2027) – 23%	FY 3 (FFY 2028) – 25%
115	158	206
Projected Immigration of Patients		
FY 1 (FFY 2026) – 10.32%	FY 2 (FFY 2027) – 10.32%	FY 3 (FFY 2028) – 10.32%
13	18	24
Projected Retained WakeMed Patients Currently Referred Elsewhere		
FY 1 (FFY 2026) – 33%	FY 2 (FFY 2027) – 44%	FY 3 (FFY 2028) – 55%
127	166	212
Total Projected Patients		
FY 1 (FFY 2026)	FY 2 (FFY 2027)	FY 3 (FFY 2028)
255	342	442
Total ESTVs (15.96078 ESTVs per Patient)		
FY 1 (FFY 2026)	FY 2 (FFY 2027)	FY 3 (FFY 2028)
4,070	5,459	7,055

Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

WakeMed does not currently have any existing or approved LINACs owned by the applicant or a related entity in Service Area 20. As shown in the table above, WakeMed RMP projects

to serve at least 250 patients per LINAC in the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

Discussion

- Comments received during the public comment period state that counting “retreatment” patients as more than one patient are unreasonable and that without those patients, WakeMed RMP would not meet the appropriate performance standard. However, on the 2023 License Renewal Application for Hospitals, the section asking for data on LINAC utilization states the following:

“Patients shall be counted once if they receive one course of treatment and more if they receive additional courses of treatment. For example, one patient who receives one course of treatment counts as one, and one patient who receives three courses of treatment counts as three.”

WakeMed RMP’s utilization projections for “retreatment” patients are consistent with information collected by the Agency on LRAs for license renewals and for data used in need methodologies in the SMFP.

- Comments received during the public comment period suggested that it is unreasonable to use a 52.3% rate as the estimate for the percentage of all cancer patients that require radiation therapy treatment because the citation for that rate came from an article based on Australian patients which was published 18 years ago.

The Project Analyst researched the percentage of cancer patients that will require radiation therapy treatment using sources from 2019 through the present. While most current information discusses radiation therapy utilization based on the specific type of cancer, the World Health Organization, the American Cancer Society, and the Mayo Clinic all state that more than half of all cancer patients will receive radiation therapy. Please see the Working Papers for documentation. Additionally, another application in this review cites the American Cancer Society as saying that approximately two-thirds of cancer patients will need radiation therapy. See page 55 of Project ID #J-12371-23.

Projected utilization is reasonable and adequately supported based on the following reasons:

- The applicant’s assumptions are consistent with publicly available information.
- The applicant relies on data from publicly available and reliable sources such as NC OSBM.
- The applicant referred more patients out for radiation therapy in a single year than it would need to meet the relevant performance standard.

Access to Medically Underserved Groups – In Section C, page 73, the applicant states:

“WakeMed ensures access to health care services for all patients, regardless of income, payer status, gender, race, ethnicity, or [disability]. At WakeMed, the goal is to provide outstanding and thoughtful care to all who seek services.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	1.7%
Racial and ethnic minorities	30.9%
Women	70.5%
Persons 65 and older	46.7%
Medicare beneficiaries	50.8%
Medicaid recipients	4.7%

Source: Section C, page 82

The applicant does not include projections for the percentage of patients with disabilities it anticipates serving in the third full fiscal year following project completion. In Section C, pages 71-82, the applicant discusses its commitment to medically underserved groups, including specific discussions about care for persons with disabilities.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all residents of the service area, including underserved groups.
- The applicant provides its Americans with Disability Policy and its Financial Assistance Policy in Exhibit C.6.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Patient Origin – In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

Duke Garner is not an existing facility. The following table illustrates projected patient origin.

Projected Patient Origin – Duke Garner						
ZIP Code	FY 1 – SFY* 2027		FY 2 – SFY* 2028		FY 3 – SFY* 2029	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
27520	9	8%	17	9%	21	8%
27529	13	11%	24	13%	31	11%
27545	8	7%	15	8%	21	8%
27592	6	5%	10	5%	13	5%
27601	6	5%	9	5%	13	5%
27604	10	9%	14	7%	22	8%
27605	5	4%	8	4%	11	4%
27608	6	5%	9	5%	13	5%
27610	13	11%	22	11%	33	12%
27539	9	7%	15	8%	22	8%
27603	12	10%	19	10%	29	11%
27606	8	6%	13	7%	19	7%
Inmigration	11	9%	18	9%	25	9%
Total	116	100%	193	100%	273	100%

Source: Section C, page 33

Note: Table may not foot due to rounding.

*SFY – State Fiscal Year (July 1 – June 30)

In Section Q, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions and methodology used to project patient origin are not reasonable and adequately supported because the applicant’s utilization projections are not reasonable and adequately supported. See the discussion below regarding projected utilization for additional information.

Analysis of Need – In Section C, pages 36-41, the applicant explains the reasons why it believes the population projected to utilize the proposed services needs the proposed services, which are summarized below.

- The applicant states its existing LINACs have experienced significant growth. The applicant states that there was a disruption in care during the COVID-19 pandemic, reducing utilization, and there has been a return to historical growth patterns. (page 37)
- The applicant states that, according to NC OSBM, the projected rate of population growth in Wake County between July 1, 2020 and July 1, 2030 will be nearly double that of the state as a whole. The applicant further states that, according to NC OSBM, the Wake County population aged 65 and older will grow at more than double the rate of the Wake County population as a whole. (pages 38-39)

- The applicant states that, according to Sg2, ZIP codes within a 20-minute drive of the proposed Duke Garner will increase their population by an average of 6.4% between 2023 and 2028. The applicant states there is only one existing LINAC within that area which does not appear to have capacity and which forces patients in that area to travel further distances to reach other LINACs. (page 39)
- The applicant states developing Duke Garner will not only allow coordination between other medical services, such as physician services, imaging, and ambulatory surgery services, but will also allow for a local access point to coordinated care provided by the Duke Cancer Institute. (pages 39-41)
- The applicant states that there is “...a broad, proven MRI referral base which supports vital patient care throughout the Triangle and beyond, including oncology screening and treatment.” (page 41)

However, the information provided by the applicant is not reasonable and adequately supported based on the following reasons:

- The applicant states that its strong provider support is evidence of the need for LINAC services at Duke Garner. The applicant discusses the referral base for MRI patients and how primary care providers refer patients for MRI screening and specialists that rely on MRI screening. The applicant states that there will be a primary care practice in the same location where the LINAC will be developed.

However, the applicant provides no information in the application as supported to explain why the location of a primary care clinic in the same place at the proposed LINAC demonstrates the need for a LINAC in that location. The applicant also provides no information as to what correlation, if any, exists between a broad MRI referral base and the need for additional LINAC services.

- The adjusted need determination for the LINAC is the result of a petition to the SHCC from WakeMed. Duke submitted comments in response to that petition. Duke’s comments stated, in part:

“Duke supports the application of the existing methodology and resulting determination that no need exists for additional equipment in the service area.

...

One of the linear accelerators...has been approved for acquisition and relocation into Wake County by Duke. The other is under development by UNC. In light of the fact that the two identified ‘underutilized’ linear accelerators are in fact both projects that are under development and projected to be available to increase access for patients in the near future and are not simply chronically underutilized, it is premature to determine that there is insufficient inventory to meet the future needs of the service area.”

Duke does not provide any information in the application as submitted as to what changed in the eight months between the deadline for comments in response to Summer 2022 petitions (August 10, 2022) and the application deadline for this review cycle (April 17, 2023) that now causes them to believe that there is an additional need for LINAC services in Service Area 20. Further, Duke’s comments are premised in part on the fact that two LINACs in Service Area 20 are under development and therefore any determination of insufficiency is premature; however, the two LINACs are still under development as of the date of these findings, and Duke does not provide any information in the application as submitted to explain the discrepancy in its position in August 2022 and its application in April 2023.

Projected Utilization – On Form C.2b in Section Q and in the Assumptions – Form C subsection of Section Q, the applicant provides projected utilization, as illustrated in the following table.

Duke Garner LINAC –Projected Utilization			
	FY 1	FY 2	FY 3
	SFY 2027	SFY 2028	SFY 2029
# of Units	1	1	1
# of ESTV Treatments*	1,972	3,281	4,641
# of Patients	116	193	273

*ESTV = Equivalent Simple Treatment Visits

In the Assumptions – Form C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant used ZIP codes to delineate geographical boundaries and isolated “catchment areas” for its approved but not yet developed Duke Green Level LINAC and the proposed Duke Garner LINAC. The applicant defined its catchment areas as ZIP codes within 20 minutes driving time of a facility. Three of the ZIP codes are in both the Duke Green Level and the Duke Garner catchment areas.
- The applicant identified the SFY 2022 radiation procedures at all Duke sites (including sites in Durham County) by ZIP code and projected procedures would increase at a 1.3% annual rate through SFY 2029.
- The applicant projects the percentage of procedures that will shift from existing Duke locations to the Duke Green Level and Duke Garner facilities. The applicant projects procedures from the ZIP codes closest to the new facilities will be more likely to shift than ZIP codes further away. The applicant states it reduced the projections for the three ZIP codes that were in both the Duke Green Level and Duke Garner catchment areas because patients will have multiple options to choose from.
- The applicant divided the number of procedures by 17, the ratio of patients to ESTVs that was reported for Duke Raleigh Hospital’s LINACs in the 2023 SMFP, to determine the number of patients that would shift.

- The applicant projected a statewide use rate using its ratio of 17 ESTVs/patient applied to the combined total ESTVs reported statewide in the 2023 SMFP. The applicant calculated a use rate of 3.5 patients per 1,000.
- The applicant applied the use rate to the 2021 populations of both catchment areas and calculated the estimated total number of LINAC patients in each catchment area. The applicant then subtracted the number of its actual existing patients in each catchment area in 2021 to determine the percentage of market share it currently has. The applicant determined it has a 20% market share in its Duke Garner catchment area and 36% in its Duke Green Level catchment area.
- The applicant projected a 6.5% increase in market share for the Duke Garner catchment area. The applicant states this will happen due to the proximity of LINAC services, access to Duke Cancer Institute services, and coordination with other types of care at the Duke Garner site. The applicant projects a ramp-up period in the gain in market share during each of the first three full fiscal years following project completion.
- The applicant projected a 3% increase in market share for the Duke Green Level catchment area. The applicant states the projected gain in market share will be lower because there are more options for LINAC services in that catchment area and market share increase will potentially be lower as a result.
- The applicant states that 23% of LINAC patients at Duke Raleigh Hospital originate from outside of Service Area 20. The applicant then projects an in-migration rate of 10% for both Duke Green Level and Duke Garner.

The applicant’s assumptions and methodology are summarized in the table below.

Duke Garner – Projected Utilization							
	Interim				Projected		
	SFY 2023	SFY 2024	SFY 2025	SFY 2026	FY 1 SFY 2027	FY 2 SFY 2028	FY 3 SFY 2029
# of Radiation Oncology Procedures (1.3%)	23,606	23,914	24,225	24,540	24,860	25,183	25,511
Duke Garner							
# Procedures Shifting to Duke Garner					866	1,585	2,369
# of Patients Shifting to Duke Garner*					51	93	139
Market Share Increase Duke Garner (6.5%)					55	82	109
In-migration – Duke Garner (10%)					11	18	25
Total Patients – Duke Garner					116	193	273
Green Level							
# Procedures Shifting to Duke Green Level					1,760	2,836	3,938
# of Patients Shifting to Duke Green Level*					103	166	231
Market Share Increase Duke Green Level (3%)					43	65	87
In-migration – Duke Green Level (10%)					15	23	32
Total Patients – Duke Green Level					161	255	350

*Based on a ratio of 17 procedures per patient.

Duke Health System – Service Area 20 – Pursuant to 10A NCAC 14C .1903(e), an applicant proposing to add a LINAC must project that all LINACs in the service area owned or operated by the applicant or a related entity will perform at least 6,750 ESTVs per LINAC or serve at least 250 patients per LINAC in the third full fiscal year following project completion.

In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all Duke LINACs in Service Area 20, which are summarized below.

- The applicant projected utilization for the approved but not yet operational Duke Green Level LINAC with the same projections as Duke Garner.
- The applicant projected utilization at all of its Duke Raleigh Hospital LINACs by applying different projected growth rates to the historical patients based on where those historical patients originated from:
 - ZIP codes in Duke Garner catchment area: 1.3%
 - ZIP codes in Duke Green Level catchment area: 1.3%
 - Other ZIP codes in Wake County: 1.4%
 - Durham County: 1.0%
 - Other NC Areas: 1.1%
- The applicant then subtracted the Duke Green Level and Duke Garner patients projected to shift from existing LINACs operated by Duke in Wake County.

The applicant’s calculations result in the following utilization projections.

Duke Health System LINAC Utilization – Service Area 20									
	Patients							# LINACs	Patients/ LINAC
	SFY 2023	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028	SFY 2029		
Duke Cary	364	369	374	365	348	330	311	1	311
Duke Raleigh Hospital	574	582	589	578	567	546	522	2	261
Women’s Cancer Care	306	310	314	308	302	290	277	1	277
Duke Green Level				68	161	255	350	1	350
Duke Garner				43	116	193	273	1	273
Total	1,244	1,261	1,277	1,362	1,494	1,614	1,733	6	289

As shown in the table above, each individual LINAC as well as the average utilization across all LINACs owned and operated by Duke in Service Area 20 are projected to exceed 250 patients per LINAC during the third full fiscal year following project completion. This meets the performance standard required by 10A NCAC 14C .1903(e).

However, projected utilization is not reasonable and adequately supported based on the following reasons:

- In Section Q, the applicant states the following:

“..., the highest anticipated shift is 50% for the closest zip [sic] codes to the new LINAC locations, with lower anticipated shifts for other zip [sic] codes. DUHS also anticipates that for those zip [sic] codes that may be within a 20-minute drive of either Garner or Green Level will have a lower shift rate to each facility since patients will have both options.”

However, the applicant does not project a shift of 50% for any of the ZIP codes with patients projected to shift to Duke Green Level. The applicant projects no more than 20% of the patients in a given ZIP code in the Duke Green Level catchment area will shift to Duke Green Level. In contrast, the applicant projects that no less than 30% of patients in ZIP codes in the Duke Garner catchment area will shift to Duke Garner. In responses to public comments, the applicant states the application as submitted explains that some ZIP codes will have lower shifts due to having access to multiple options for treatment sites; however, that is not consistent with the representations in the application as submitted. The applicant makes that statement about the three ZIP codes that are in both the Duke Garner and Duke Green Level catchment area, not about other ZIP codes.

- The applicant projects patient shifts that are not consistent with the assumptions it provides in the application as submitted.

The applicant states that the ZIP codes closest to Duke Green Level and Duke Garner will have the highest patient shifts, with ZIP codes being further away having lower patient shifts and ZIP codes with multiple options for treatment centers having lower shifts. However, the applicant projects higher patient shifts from certain ZIP codes that have multiple treatment options located closer than Duke Garner while projecting lower patient shifts from ZIP codes closer to Duke Garner.

For example, ZIP code 27608 is located near the center of Raleigh. The applicant projects that 45% of patients in ZIP code 27608 will shift to Duke Garner. However, the LINACs at Duke Raleigh Hospital and Duke Cary are significantly closer to all of ZIP code 27608 than to Duke Green Level or to Duke Garner. The applicant does not explain in the application as submitted why the shift for this ZIP code is so high, while the shift for ZIP codes 27605 and 27601 – both ZIP codes closer to Duke Garner than ZIP code 27608 is to Duke Garner – is projected to be only 30%.

Access to Medically Underserved Groups – In Section C, page 46, the applicant states:

“The services of Duke University Health System facilities, including the proposed radiation oncology services, are open to all area and non-area residents. Policies to provide access to services by low income, medically indigent, uninsured, or underinsured patients are described and provided elsewhere in this application. The facility will meet all ADA requirements for physical accessibility.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	8.0%
Racial and ethnic minorities	24.2%
Women	50.5%
Persons 65 and older	45.0%
Medicare beneficiaries	47.9%
Medicaid recipients	6.1%

Source: Section C, page 46

On page 46, the applicant states data on the number of persons with disabilities is unavailable.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement saying it will provide service to all patients regardless of location.
- The applicant provides documentation of its existing policies regarding non-discrimination and patients' rights in Exhibit C.6.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – All Applications

None of the applicants propose to reduce a service, eliminate a service, or relocate a facility or 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.

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park**

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section E, pages 84-85, 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 that maintaining the status quo would not reduce utilization demands at UNC Rex Wakefield, which has the most heavily utilized LINAC in Service Area 20. The applicant further states additional capacity is needed because of the population growth in Service Area 20; therefore, this was not an effective alternative.
- Develop the LINAC at a Different Facility in Wake County – The applicant states developing the LINAC at a different facility would not meet the needs of the service area as effectively, especially for Franklin County residents, and would not introduce a new service at UNC Rex Wakefield that is currently unavailable at that location; therefore, this was not an effective alternative.
- Develop the LINAC in Franklin County – The applicant states this alternative would require additional construction costs, would replicate existing services, and the population of Franklin County along with travel patterns in Wake County would not support the placement of a LINAC in Franklin County; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project and did not demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be an effective alternative to meet the need.
- The applicant does not demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. A proposal that cannot demonstrate it will be financially feasible cannot be an effective alternative to meet the need.
- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved services in Service Area 20. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A

proposal that cannot demonstrate it is not an unnecessary duplication of existing and approved services in the service area cannot be an effective alternative to meet the need.

- The applicant does not demonstrate that any enhanced competition from the proposed project will have a positive impact on cost-effectiveness. The discussion regarding enhanced competition and the impact on cost-effectiveness found in Criterion (18a) is incorporated herein by reference. A proposal that cannot demonstrate how any enhanced competition will have a positive impact on cost-effectiveness cannot be an effective alternative to meet the need.
- The application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section E, pages 89-92, 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 that maintaining the status quo would result in the patients who seek WakeMed for cancer care would not be able to receive radiation therapy at WakeMed and must go to one of the other two health systems in Wake County. The applicant states that waits are already disproportionately long; therefore, this was not an effective alternative.
- Work with a Different Health System – The applicant states it had a joint venture with Duke Health in the late 2010s, Cancer Care Plus+, but that program dissolved by mutual agreement. The applicant states its cancer patients wait longer to receive radiation therapy than the average Wake County patient and delays caused by care fragmentation are made worse for people who are medically underserved; therefore, this was not an effective alternative.

- Wait for a Need Determination in a Future SMFP – The applicant states the existing LINACs in Wake County are not operating at the level that would trigger a need determination and that both Duke and UNC have approved LINACs that are not operational; therefore, this was not an effective alternative.
- Acquire Different Equipment – The applicant states new equipment represents a better investment for the planned purposes of the community cancer program and choosing equipment with more advanced features and functions would be more difficult to maintain and only serve a fraction of WakeMed patients; therefore, this was not an effective alternative.
- Develop a Freestanding Radiation Oncology Center – The applicant states the logistics necessary to seek accreditation, licensure, and coordination with WakeMed would delay the process significantly, and that it would potentially result in more bills sent to patients; therefore, this was not an effective alternative.
- Locate the LINAC Elsewhere in Service Area 20 – The applicant states the resources are already in place at WakeMed that would facilitate this specialty service. The applicant states Franklin County is not yet populous enough to support stand-alone specialty services and that Duke is relocating the LINAC from Franklin County to Wake County for that reason; therefore, this was not an effective alternative.

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section E, page 55, 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 maintaining the status quo would not expand geographic access to patients in the Garner area or meet the need identified in the 2023 SMFP; therefore, this was not an effective alternative.
- Develop the LINAC in a Different Location – The applicant states Garner is a fast-growing part of the service area and does not have radiation oncology services; therefore, this was not an effective alternative.
- Develop the LINAC in an Existing Medical Office Building – The applicant states it does not have any space in any buildings under development for the equipment and support space required; therefore, this was not an effective alternative.
- Develop Other Affiliations – The applicant states it is willing to consider other affiliations to offer the proposed services but has not identified one that would meet the need; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project and did not demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference. A proposal that is not needed by the population proposed to be served cannot be an effective alternative to meet the need.
- The applicant does not demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses. The discussion regarding financial feasibility found in Criterion (5) is incorporated herein by reference. A proposal that cannot demonstrate it will be financially feasible cannot be an effective alternative to meet the need.
- The applicant does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved services in Service Area 20. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A proposal that cannot demonstrate it is not an unnecessary duplication of existing and approved services in the service area cannot be an effective alternative to meet the need.
- The applicant does not demonstrate that any enhanced competition from the proposed project will have a positive impact on cost-effectiveness. The discussion regarding enhanced competition and the impact on cost-effectiveness found in Criterion (18a) is incorporated herein by reference. A proposal that cannot demonstrate how any enhanced

competition will have a positive impact on cost-effectiveness cannot be an effective alternative to meet the need.

- The application is not conforming to all other statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park**

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

Capital and Working Capital Costs – On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contracts	\$4,833,374
Architect/Engineering/Consultant Fees	\$824,006
Medical Equipment	\$3,399,998
Non-Medical Equipment/Furniture	\$188,483
Other (Contingency, DHSR Fees)	\$1,329,693
Total	\$10,575,554

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides assumptions about costs included in the calculation of each line item in the projected capital cost.

- The applicant states much of the projections are based on the applicant's history or the project architect's history in developing similar projects.
- In Exhibit F.1, the applicant provides a registered architect's certification dated March 3, 2023, stating the construction costs listed (which match those listed in Form F.1a) are accurate.
- The applicant provides a quote for the proposed LINAC in Exhibit C.1-2.

In Section F, page 89, the applicant states that there are no projected start-up expenses or initial operating expenses because the project does not involve a new service. This information is reasonable and adequately supported because UNC Rex Wakefield is an existing facility currently offering LINAC services and will continue to offer LINAC services during and after development of the proposed project.

Availability of Funds – In Section F, pages 87-88, the applicant states the entire projected capital expenditure of \$10,575,554 will be funded with Rex's accumulated reserves.

In Exhibit F.2-1, the applicant provides a letter dated April 17, 2023 from the Chief Financial Officer for Rex Hospital, Inc., stating that Rex Hospital, Inc. has sufficient accumulated reserves to fund the projected capital cost and committing to providing that funding to develop the proposed project.

Exhibit F.2-2 contains a copy of Rex Healthcare, Inc. and Subsidiaries Combined Financial Statements for the years ending June 30, 2022 and 2021. According to the Combined Financial Statements, as of June 30, 2022, Rex Hospital, Inc. had adequate cash and assets to fund all the capital needs of the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Rex Hospital, Inc. official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund 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 project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – UNC Rex Wakefield Radiation Oncology			
	FY 1 (SFY 2026)	FY 2 (SFY 2027)	FY 3 (SFY 2028)
Total Patients	740	752	766
Total Gross Revenues (Charges)	\$13,889,862	\$14,512,636	\$15,196,700
Total Net Revenue	\$5,954,859	\$6,221,854	\$6,515,126
Total Net Revenue per Patient	\$8,047	\$8,274	\$8,505
Total Operating Expenses (Costs)	\$3,902,566	\$4,299,179	\$4,403,599
Total Operating Expenses per Patient	\$5,274	\$5,717	\$5,749
Net Profit/(Loss)	\$2,052,293	\$1,922,675	\$2,111,528

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Capital and Working Capital Costs – On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contracts	\$3,095,580
Architect/Engineering/Consultant Fees	\$436,947
Medical Equipment	\$5,175,776
Non-Medical Equipment/Furniture	\$375,000
Other*	\$518,580
Total	\$9,601,883

*"Other" includes project testing, permits, fees, IAQ, communications, security, artwork & signage, and contingency.

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit C.1, the applicant includes price quotes for the LINAC and CT simulator.
- In Exhibit K.1, the applicant provides a letter from a licensed architect, stating that the projected capital costs are “*a reasonable estimate of the costs to be expected on a project of the scope and complexity defined.*”
- In Exhibit K.1, the applicant provides a detailed breakdown of capital costs, including information about costs per gross square foot.

In Section F, page 96, the applicant provides assumptions for initial operating costs and start-up costs as an illustration. The applicant states it is an existing acute care hospital with an established cash flow. This information is reasonable and adequately supported because WakeMed RMP will be licensed under WakeMed, an existing facility with a cancer care program.

Availability of Funds – In Section F, page 94, the applicant states the projected capital cost of \$9,601,883 will be funded by WakeMed’s accumulated reserves.

In Exhibit F.2, the applicant provides a letter dated April 12, 2023 from the Senior Vice President, Finance & Interim Chief Financial Officer at WakeMed Health & Hospitals, committing to funding the capital cost of \$9,601,883 with accumulated reserves.

Exhibit F.2 also contains a copy of the WakeMed Combined Financial Report with Supplementary Information for the year ending September 30, 2022. According to the Combined Financial Report, as of September 30, 2022, the applicant had \$867,151,000 in unrestricted reserves, which is adequate to fund both the projected capital cost and the illustrative working capital costs.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate WakeMed official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund 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 project completion. On Form F.2b in Section Q, the applicant projects revenues will exceed operating expenses in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – WakeMed RMP			
	FY 1 (FY 2026)	FY 2 (FY 2027)	FY 3 (FY 2028)
Total Patients	255	342	442
Total Gross Revenues (Charges)	\$11,240,068	\$15,547,259	\$20,672,890
Total Net Revenue	\$3,703,739	\$5,081,011	\$6,698,020
Total Net Revenue per Patient	\$14,524	\$14,857	\$15,154
Total Operating Expenses (Costs)	\$2,880,340	\$4,583,630	\$5,398,833
Total Operating Expenses per Patient	\$11,295	\$13,402	\$12,213
Net Profit/(Loss)	\$823,399	\$497,381	\$1,299,187

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly details the sources of data used to project revenues and expenses.
- The applicant bases projections on its own historical experience.
- The applicant accounts for the potential future impact of Medicaid expansion in North Carolina.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
- 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 revenues and operating expenses for all the reasons described above.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Capital and Working Capital Costs – On Form F.1a in Section Q, the applicant projects the total capital cost of the project, as shown in the table below.

Site Preparation/Landscaping	\$1,300,000
Construction/Renovation Contracts	\$16,173,950
Architect/Engineering Fees	\$2,007,500
Medical Equipment	\$4,700,000
Non-Medical Equipment/Furniture	\$3,750,000
Other (Contingency, Filing)	\$5,586,550
Total	\$33,518,000

The applicant provides its assumptions and methodology for projecting capital cost immediately following Form F.1a in Section Q. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant states much of the projections are based on the applicant’s history in developing similar projects.
- In Exhibit F.1(a), the applicant provides quotes for the proposed LINAC and CT simulator.
- In Exhibit F.1(b), the applicant provides a registered architect’s certification dated April 3, 2023, stating the construction costs listed (which match those listed in Form F.1a) are accurate and reasonable.

In Section F, pages 57-58, the applicant projects start-up costs of \$316,002 and projects a 3.5-year initial operating period and \$3,385,218 in initial operating costs for a projected total of \$3,701,220 in working capital costs. The applicant provides its assumptions and methodology for projecting working capital cost on pages 58-59. The applicant adequately demonstrates that the projected working capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the different components of the start-up expenses projected.
- The applicant provides the calculations to show that there will be negative net revenue through the end of the third full fiscal year following project completion.

Availability of Funds – In Section F, pages 56 and 59, the applicant states the entire projected capital expenditure of \$33,518,000 and the entire working capital expenditure of \$3,701,220 will be funded with Duke’s accumulated reserves.

In Exhibit F.2(a), the applicant provides a letter dated April 12, 2023 from the Vice President, Finance – Corporate Controller and Treasurer of DUHS, stating Duke has sufficient

accumulated reserves to fund the projected capital and working capital costs and committing to providing that funding to develop the proposed project. The letter also states:

“We would note that FY 2024 reflects a significant operating loss due in part to an investment in acquiring and integrating the Duke faculty physician practice into the health system. We anticipate a return to profitability by FY 2029. In the interim, DUHS is committed to funding continued operations and capital investments from accumulated reserves, and has sufficient reserves to ensure the financial feasibility of this project and its operations overall.”

Form F.2b in Section Q shows that the Duke system (including the proposed project) will incur approximately \$1,082,502,000 in operating losses between now and the end of the third full fiscal year following project completion.

Exhibit F.2(b) contains a copy of Duke University Health System, Inc. and Affiliates Consolidated Financial Statements and Supplementary Schedules for the years ending June 30, 2022 and 2021. According to the Consolidated Financial Statements, as of June 30, 2022, Duke had \$1,376,395,000 in current assets (excluding assets limited as to use), which is sufficient to fund the proposed capital expenditure, proposed working capital expenditure, and any system losses through the third full fiscal year following project completion.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides a letter from the appropriate Duke official confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.
- The applicant provides adequate documentation of the accumulated reserves it proposes to use to fund 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 project completion. On Form F.2b in Section Q, the applicant projects operating expenses will exceed revenue in each of the first three full fiscal years following project completion, as shown in the table below.

Revenues and Operating Expenses – Duke Garner			
	FY 1 (SFY 2027)	FY 2 (SFY 2028)	FY 3 (SFY 2029)
Total Patients	116	193	273
Total Gross Revenues (Charges)	\$6,278,249	\$10,449,674	\$14,780,679
Total Net Revenue	\$1,501,602	\$2,544,842	\$3,664,796
Total Net Revenue per Patient	\$12,945	\$13,186	\$13,424
Total Operating Expenses (Costs)	\$5,437,291	\$5,791,128	\$5,971,791
Total Operating Expenses per Patient	\$46,872	\$30,006	\$21,875
Net Profit/(Loss)	(\$3,935,689)	(\$3,246,286)	(\$2,306,994)

The applicant also provided pro forma financial statements for the Duke system for the first three full fiscal years of operating following project completion. The applicant projects revenue will exceed operating expenses by the third full fiscal year of operation following project completion, as shown in the table below.

Revenues and Operating Expenses – DUHS			
	FY 1 (SFY 2027)	FY 2 (SFY 2028)	FY 3 (SFY 2029)
Total Gross Revenues (Charges)	\$22,748,151,000	\$23,682,833,000	\$24,655,396,000
Total Net Revenue	\$6,916,399,000	\$7,188,183,000	\$7,474,213,000
Total Operating Expenses (Costs)	\$7,040,310,000	\$7,245,457,000	\$7,459,321,000
Net Profit/(Loss)	(\$123,911,000)	(\$57,274,000)	\$14,891,000

The assumptions used by the applicant in preparation of the pro forma financial statements are provided immediately following Form F.3b in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
 C – WakeMed Raleigh Medical Park**

The 2023 SMFP includes an adjusted need determination for one LINAC in Service Area 20.

In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 existing and approved LINACs associated with five different facilities in Service Area 20. Information about each of the facilities and utilization of the LINACs in Service Area 20 during FFY 2021 is provided in the table below.

Service Area 20 LINACs				
Facility	County	# of LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC
Franklin County Cancer Center*	Franklin	1	0	0
Duke Raleigh Hospital	Wake	4	21,075	5,269
UNC Hospital Radiation Oncology – Holly Springs**	Wake	1	0	0
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148
UNC Rex Hospital	Wake	4	21,639	5,410
Total		11	47,862	4,351

Source: Table 17C-1, 2023 SMFP

*Project ID #J-12000-20 authorized the replacement and relocation of this LINAC to Cary, in Wake County. The project is still under development.

**Approved but not yet developed.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section G, page 97, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

“The proposed project will allow UNC Health Rex to ensure capacity for future growth and expand the availability of radiosurgery treatments to the Cancer Care of Wakefield facility. This will improve accessibility for residents of northern Wake and Franklin counties. The proposed LINAC at Cancer Care of Wakefield is needed to accomplish UNC Health Rex’s strategy for creating a geographically diverse complement of cancer care resources that maximize accessibility and high quality care for the entire population of Service Area 20. The proposed LINAC is necessary, given the growing population within the service area, the increasing number of residents age 65 and older, the health disparities for communities in Franklin County, the operational efficiencies of having a second LINAC at the Cancer Care of Wakefield facility, and the resulting enhancements for the patient experience. Moreover, the proposed LINAC will bring, for the first time, SRS and SBRT capabilities to northern Wake and Franklin counties, expanding access to this life-saving technology. The proposed LINAC at Cancer Care of Wakefield will not result in the unnecessary duplication of existing services.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following reasons:

- The applicant does not demonstrate the need the population proposed to be served has for the proposed services or that projected utilization is based on reasonable and adequately

supported assumptions. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference. An application that cannot demonstrate that the population proposed to be served needs the proposed services cannot demonstrate that the project will not be an unnecessary duplication of existing or approved services.

- The UNC System has an existing certificate of need for a LINAC, issued nearly seven and a half years ago, that has not been developed. The applicant does not demonstrate that the proposed LINAC is not an unnecessary duplication when it has not developed the LINAC approved nearly seven and a half years ago.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section G, pages 106-107, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

“...neither Service Area 20 nor Harnett and Johnston Counties [sic] have excess linear accelerator capacity today in operational equipment. WakeMed’s experience with patient waits shows this is affecting patient care. Close review of individual facilities affirms low capacity.

...

..., UNC Rex East Raleigh linear accelerator operated above the Performance Standard in 10A NCAC 14C.1903(5) for patients served in FY 2021. This linear accelerator served the highest ratio of patients per unit in the service area. Its proximity to WakeMed Raleigh Campus, combined with WakeMed patients’ high wait times for radiation therapy, lends credence to the notion that demand for LINAC services is high and that service area need will continue to grow.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2023 SMFP for the proposed linear accelerator in Service Area 20.
- The applicant adequately demonstrates that the proposed linear accelerator is needed in addition to the existing or approved linear accelerators in Service Area 20.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section G, pages 65-66, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing linear accelerator services in Service Area 20. The applicant states:

“The State Medical Facilities Plan includes a need determination for an additional linear accelerator in Service Area 20. DUHS evaluated and developed this specific proposal in response to the state identified need determination to provide radiation oncology services in a new service location that will not create any unnecessary duplication of existing or approved health service facilities.

...

There are no services currently locally available in Garner, a fast-growing part of Wake County. This project will meet the need for additional capacity identified in the SMFP in a new location and therefore will not unnecessarily duplicate existing or approved capacity that may exist or be in development elsewhere in the service area.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant does not demonstrate the need the population proposed to be served has for the proposed services or that projected utilization is based on reasonable and adequately supported assumptions. The discussions regarding need and projected utilization found in Criterion (3) are incorporated herein by reference. An application that cannot demonstrate that the population proposed to be served needs the proposed services cannot demonstrate that the project will not be an unnecessary duplication of existing or approved services.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

On Form H in Section Q, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

UNC Rex Wakefield LINAC – Current & Projected FTEs			
	Current (6/30/2022)	FY 1 (SFY 2026)	FYs 2-3 (SFYs 2027-2028)
Administrative Support	1.0	1.0	1.0
Clinical Support – CMA	0.0	0.0	1.0
Nurse	1.0	1.0	1.0
Radiation Therapist	2.0	5.0	5.0
Radiation Coordination Supervisor	1.0	1.0	1.0
Dosimetrist	0.5	1.5	2.0
Physicist	1.0	1.5	2.0
Manager	0.5	0.5	0.5
Total	7.0	11.5	13.5

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 99-100, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs and provides supporting documentation in Exhibit B.20-2.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.

- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.
- In Exhibit B.20-2, the applicant provides policies and guidelines provided to staff at UNC Rex Wakefield.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

WakeMed RMP Projected FTEs			
	FY 1 (FY 2026)	FY 2 (FY 2027)	FY 3 (FY 2028)
Registered Nurses	2.00	2.00	2.00
Radiation Oncologist	1.00	1.25	1.75
Lead Radiation Therapist	1.00	1.00	1.00
Radiation Therapist	2.00	3.00	4.10
PAR (reception)	2.00	2.00	2.00
Total	8.00	9.25	10.85

The assumptions and methodology used to project staffing are provided in Section Q on Form F.3b and Form H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 109-117, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services.
- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

On Form H in Section Q, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Duke Garner LINAC – Projected FTEs	
	FYs 1-3 (SFYs 2027-2029)
Registered Nurses	2.24
Information Technology	0.06
Administrator/CEO	0.06
Radiation Therapist	4.76
Dosimetrist	2.28
Chief Dosimetrist	0.28
Chief Radiation Therapist	1.12
Regional Director	0.28
Financial Care Counselor	1.12
Patient Service Associate	1.12
Total	13.31

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Section H, pages 67-68, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. Supporting documentation is provided in Exhibit H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately documents the number of FTEs it projects will be needed to offer the proposed services and the modeling it used to project FTEs.
- The applicant accounts for projected salaries and other costs of employment for FTEs in its projected operating expenses found on Form F.3b in Section Q.
- In Exhibit H.3, the applicant provides the Duke system policy on continuing education.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

Ancillary and Support Services – In Section I, page 102, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 102-103, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is currently providing the necessary ancillary and support services at the same facility where it proposes to develop the additional LINAC.
- In Exhibit I.1, the applicant provides a letter from the president of Rex Hospital, Inc., attesting to the existence of the necessary ancillary and support services and committing to continue to provide the necessary ancillary and support services for the proposed project.

Coordination – In Section I, page 103, the applicant describes UNC Rex Wakefield’s existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- UNC Rex Wakefield is an existing facility and thus has established many relationships with area healthcare providers.
- In Exhibit I.2, the applicant provides letters of support from local physicians and healthcare providers documenting their support for UNC Rex Wakefield and the proposed project.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Ancillary and Support Services – In Section I, page 118, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 119-120, the applicant explains how each ancillary and support service is made available and provides supporting documentation in Exhibits C.1, H.2, and I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is currently providing many of the necessary ancillary and support services at the adjacent hospital campus and the proposed facility will be licensed as part of the hospital.
- In Exhibit I.1, the applicant provides a letter dated March 24, 2023 from the Senior Vice President & Administrator at WakeMed Raleigh Campus, attesting to the existence of the necessary ancillary and support services at WakeMed and committing to provide the necessary ancillary and support services at WakeMed RMP.

Coordination – In Section I, pages 120-122, the applicant describes WakeMed RMP's existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 1.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- WakeMed RMP will be part of the WakeMed Raleigh Campus, which is an existing hospital with many established relationships with area healthcare providers.
- In Exhibit I.2, the applicant provides letters of support from local physicians and healthcare providers documenting their support for WakeMed RMP and the proposed project.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Ancillary and Support Services – In Section I, page 69, the applicant identifies the necessary ancillary and support services for the proposed services. In Section I, pages 69-70, the applicant explains how each ancillary and support service is made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant states the services will be provided by existing Duke departments that already provide the necessary ancillary and support services at Duke’s existing radiation oncology sites.
- The applicant explains that professional services will bill payors separately for services.

Coordination – In Section I, page 70, the applicant describes Duke Garner’s proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit C.4. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Duke and Duke Cancer Institute are existing facilities with many established relationships with area healthcare providers.
- In Exhibit C.4, the applicant provides letters of support from local physicians and healthcare providers documenting their support for Duke Garner and the proposed project.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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 – All Applications

None of the applicants 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, none of the applicants 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 – All Applications

None of the applicants are HMOs. 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section K, page 106, the applicant states that the project involves constructing 2,507 square feet of new space and renovating 1,917 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

In Section K, page 107, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that while the construction involves specialized materials and techniques, the proposed construction and renovation is much more cost-effective than an entirely new building.
- The applicant plans to develop the LINAC adjacent to the existing LINAC at the same location, which the applicant states will minimize impacts of construction and help streamline patient flow.

In Section K, pages 107-108, 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 based on the following:

- The applicant describes its “conservative fiscal management” that has allowed it to pay for projects such as the project proposed in this application.
- The applicant states the proposal is designed to minimize cost by utilizing existing resources.
- The applicant states that efficiencies of scale that result from being part of UNC Health provide significant cost savings.

In Section B, page 33, 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
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section K, page 125, the applicant states that the project involves renovating 10,823 square feet of existing space in a medical office building under development. Line drawings are provided in Exhibit K.1.

In Section K, pages 129-130, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed radiation therapy center based on the applicant's representations and supporting documentation.

In Section K, page 126, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states developing the proposed project in a medical office building will cost nearly two-thirds less per square foot than developing the proposed project in a hospital.
- The applicant states multiple building designs were considered before deciding on the proposed design, in order to provide the most effective layout for patients, caregivers, and vehicles.
- The applicant states that it is familiar with local zoning ordinances and state and federal requirements for developing health service facilities and will be able to work with architectural and engineering firms that are also familiar with the requirements.

In Section K, pages 126-127, 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 based on the following:

- The applicant states the proposed project will save costs and benefit from economies of scale.
- The applicant states its established referral network and existing services will mean it reaches a breakeven point in a short amount of time.
- The applicant states it will offset any potential cost increases with its charity care program.
- The applicant states that its status as a Disproportionate Share Hospital means it will continue to serve many at-risk patients that might otherwise go without care.

In Section K, pages 127-128, 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
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section K, page 73, the applicant states that the project involves constructing 14,870 square feet of new space. Line drawings are provided in Exhibit K.1.

In Section K, pages 75-76, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site. The site appears to be suitable for the proposed radiation oncology center based on the applicant's representations.

In Section K, page 73, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states that the architect developed the projected design based on a review of actual costs for similar projects, publicly available data, and the experience of the architect.
- The applicant states that it plans to develop additional space for future services to avoid increased future expenses that would be required to develop the additional space at a future date.

In Section K, page 74, 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 based on the following:

- The applicant states that it gave careful consideration into factors related to project development so that it would not unduly increase costs to deliver services or require higher charges to consumers.
- The applicant states the proposed project will not increase the actual day-to-day operating costs of the proposed project.

In Section K, page 74, 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
- Written comments
- Responses to comments

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

- (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 ... persons [with disabilities], 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 – UNC Rex Hospital
 NA – All Other Applications**

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

In Section L, page 111, the applicant provides the historical payor mix during the last full fiscal year for all services at UNC Rex Wakefield, as shown in the table below.

UNC Rex Wakefield Historical Payor Mix – SFY 2022	
Payor Category	% of Total Patients Served
Self-Pay	1.2%
Medicare*	59.3%
Medicaid*	1.3%
Insurance*	37.0%
Other**	1.2%
Total	100.0%

*Including any managed care plans.

**Includes TRICARE.

Note: The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

In Section L, page 112, the applicant provides the following comparison.

UNC Rex Wakefield	% of Total Patients Served During SFY 2022	% of Population of Service Area
Female	60.2%	51.1%
Male	39.8%	48.9%
Unknown	0.0%	0.0%
64 and Younger	43.0%	87.4%
65 and Older	57.0%	12.6%
American Indian	0.2%	0.8%
Asian	1.2%	8.3%
Black or African-American	21.4%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	72.0%	67.1%
Other Race	3.6%	2.7%
Declined / Unavailable	1.6%	0.0%

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information which was publicly available during the review and used by the Agency

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.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC
 WakeMed RMP is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
 Duke Garner is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

- (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 ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

**C – UNC Rex Hospital
NA – All Other Applications**

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 113, the applicant states it has no such obligation.

In Section L, page 114, the applicant states that one patient civil rights access complaint was filed against UNC Rex Hospital on February 21, 2022. The applicant states:

“... Due to the nature of the allegations which included age discrimination, the complaint was referred to the Federal Mediation and Conciliation Service (FMCS). UNC Health Rex has been in contact with OCR and engaged in multiple communications with the complainant to address and resolve any and all issues. UNC Health Rex believes the matter to be closed as mediation was not required and there has been no further contact from the OCR related to this complaint.”

The applicant states that there were no other civil rights equal access complaints filed against UNC Rex Wakefield or other affiliated entity during the 18 months immediately prior to submission of the application.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

WakeMed RMP is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

Duke Garner is not an existing facility. Therefore, Criterion (13b) is not applicable to this review.

- (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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

In Section L, page 115, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

UNC Rex Wakefield Projected Payor Mix – SFY 2028		
Payor Category	% of Total Patients Served	% of LINAC Patients Served
Self-Pay	1.2%	1.4%
Medicare*	59.3%	59.2%
Medicaid*	1.3%	0.6%
Insurance*	37.0%	37.6%
Other**	1.2%	1.2%
Total	100.0%	100.0%

*Including any managed care plans.

**Includes TRICARE.

Note: The applicant states charity care is provided to patients in any payor category and that its internal data does not include charity care as a payor source.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1.2% of all services and 1.4% of LINAC services will be provided to self-pay patients, 59.3% of all services and 59.2% of LINAC services to Medicare patients, and 1.3% of all services and 0.6% of LINAC services to Medicaid patients.

On page 114, 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 based on the following:

- The projected payor mix is based on the historical payor mix.
- The applicant provides reasonable explanations for why it projects no change from the historical payor mix.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

In Section L, page 136, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

WakeMed Raleigh Campus Projected Payor Mix – FY 2028		
Payor Category	% of Total Patients Served	% of LINAC Patients Served
Self-Pay*	7.01%	1.70%
Medicare**	40.48%	50.80%
Medicaid**	18.58%	4.70%
Insurance**	28.73%	42.80%
Other***	5.20%	0.00%
Total	100.00%	100.00%

*On page 132, the applicant states charity care is included in the self-pay category.

**Including any managed care plans.

***Includes TRICARE and Workers Compensation.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 7.01% of all services and 1.70% of LINAC services will be provided to self-pay patients (including patients receiving charity care), 40.48% of all services and 50.80% of LINAC services to Medicare patients, and 18.58% of all services and 4.70% of LINAC services to Medicaid patients.

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 in Section L, page 136, and immediately following Form F.2b in Section Q. The projected payor mix is reasonable and adequately supported based on the following:

- The projected payor mix is based on the historical payor mix.
- The applicant explains why the Medicaid percentage is lower for radiation therapy services than for other services at WakeMed Raleigh Campus.
- The applicant considered the impact of the upcoming Medicaid expansion in North Carolina in making its payor mix projections.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC
In Section L, page 80, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

Duke Garner Projected Payor Mix – SFY 2029	
Payor Category	% of Total Patients Served
Self-Pay	0.3%
Charity Care	1.8%
Medicare*	47.9%
Medicaid*	6.1%
Insurance*	40.9%
TRICARE	1.1%
Other	1.8%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation following completion of the project, the applicant projects that 0.3% of services will be provided to self-pay patients, 1.8% of services to charity care patients, 47.9% of services to Medicare patients, and 6.1% of services to Medicaid patients.

On pages 80-81, 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 based on the following:

- The projected payor mix is based on the historical payor mix of patients from the proposed catchment area.
- The applicant explains the reasons adjustments were made from the actual historical payor mix to the projected payor mix.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

In Section L, page 116, 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
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

In Section L, pages 138-141, 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
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

In Section L, page 82, 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
- Written comments
- Responses to comments

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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

In Section M, pages 118-119, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- In Exhibit M.1, the applicant provides documentation of existing health professional training programs in the area which already have access to UNC Rex Wakefield.
- In Exhibit M.1, the applicant provides a copy of the clinical instruction agreement between UNC School of Nursing and Rex Healthcare, Inc.
- The applicant's parent company is an academic medical center.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

In Section M, pages 143-145, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- In Exhibit M.1, the applicant provides a list of existing health professional training programs in the area which already have access to WakeMed Raleigh Campus.
- In Exhibit M.1, the applicant provides a copy of the clinical instruction agreement between WakeMed and Pitt Community College.

- The applicant states that the existing health professional training programs in the area that have access to WakeMed Raleigh Campus will also have access to WakeMed RMP as appropriate.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

In Section M, page 83, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes because the applicant is an existing academic medical center with established health professional training programs.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

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

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
 C – WakeMed Raleigh Medical Park**

The 2023 SMFP includes an adjusted need determination for one LINAC in Service Area 20.

In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area.

There are a total of 11 existing and approved LINACs associated with five different facilities in Service Area 20. Information about each of the facilities and utilization of the LINACs in Service Area 20 during FFY 2021 is provided in the table below.

Service Area 20 LINACs				
Facility	County	# of LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC
Franklin County Cancer Center*	Franklin	1	0	0
Duke Raleigh Hospital	Wake	4	21,075	5,269
UNC Hospital Radiation Oncology – Holly Springs**	Wake	1	0	0
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148
UNC Rex Hospital	Wake	4	21,639	5,410
Total		11	47,862	4,351

Source: Table 17C-1, 2023 SMFP

*Project ID #J-12000-20 authorized the replacement and relocation of this LINAC to Cary, in Wake County. The project is still under development.

**Approved but not yet developed.

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 120, the applicant states:

“The proposed project is expected to enhance competition in Service Area 20 by promoting cost effectiveness, quality, and access to radiation oncology services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 120, the applicant discusses its “...commitment to maximizing the healthcare value for resources expended in the delivery of healthcare services, including acute care services, and the positive impact that the proposed project will have on the cost effectiveness of the proposed service.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 120, the applicant discusses its “...commitment to promoting safety and quality in the delivery of healthcare services,

including acute care services, and the positive impact that its proposed project will have on the quality of the proposed service.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 120-121, the applicant states:

“UNC Health Rex Cancer Care of Wakefield will continue to provide access to medically underserved groups in a manner consistent with UNC Health Rex Hospital’s historical experience. For members of these groups who reside in northern Wake County and Franklin County communities, access to quality cancer care will be increased and the need for a lengthy commute to UNC Health Rex Hospital’s Raleigh campus will be eliminated. The proposed project will greatly reduce the burden of coordinating transportation and caregiver resources for patients who must regularly travel to a radiation oncology facility. All UNC Health Rex facilities, including Cancer Care of Wakefield, provide care for all patients without regard to race, color, religion, creed, national origin, sex, sexual preference, disability, age, or ability to pay. Additionally, Cancer Care of Wakefield will continue to participate in both the Medicaid and Medicare programs.”

See also Sections C and L of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant did not adequately demonstrate: a) the need the population to be served has for the proposal or that projected utilization is based on reasonable and adequately supported assumptions; b) that projected revenues and operating costs are reasonable; and c) that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussions regarding demonstration of need and projected utilization, projected revenues and operating costs, and unnecessary duplication found in Criterion (3), Criterion (5), and Criterion (6), respectively, are incorporated herein by reference. A proposal that cannot demonstrate need, cannot demonstrate that projected revenues and operating costs are based on reasonable and adequately supported assumptions, and cannot demonstrate that the proposed project is not an unnecessary duplication cannot have a positive impact on cost-effectiveness.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 147, the applicant states:

“Two health systems, Duke Health, and UNC Health, own all linear accelerators in Service Area 20 (Wake and Franklin Counties). WakeMed will be a new provider of linear accelerator services in Service Area 20 and a new competitive option for radiation therapy for residents of Johnston, Harnett, and surrounding counties, as well. WakeMed is the only North Carolina hospital system of its size and complexity that does not offer radiation oncology services or is not part of a health system offering radiation oncology services within its system. Even as a hospital-based provider, WakeMed will offer pricing that is competitive with radiation oncology services at other area hospitals. WakeMed will significantly improve competitive options for access by medically underserved persons, and it has contracts with most insurance companies that have beneficiaries in the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 147-150, the applicant states:

“WakeMed’s proposal will be cost effective with regard to equipment, construction approach, funding, patient care protocols, service organization and payment value.

...

.... WakeMed proposes to acquire IMRT and IGRT software and hardware and precision IDENTIFY and HyperArc modifications that provide submillimeter precision that will spare normal tissue. These advances will save the cost of the radiation therapy protocol and more importantly, save long term costs of care for WakeMed Cancer Care patients. ...

...

The Applicant proposes to fund the project with its own accumulated reserves, thus eliminating the cost of borrowing, and limiting project costs.

...

..., WakeMed is a private, not-for-profit tertiary community health care system. It is true to its tax-exempt status and gives back to the community in the dozens of ways described in this application, at rates unmatched by many other health systems.

...

Recognizing the breadth of need in Service Area 20 and the proposed project service area, WakeMed proposes equipment and staffing that can accommodate most cancers. WakeMed will be both a new provider and one that can accommodate the wide variety of needs in this complex community.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 150-151, the applicant states:

“The proposed project will operate as part of WakeMed Raleigh Campus. This automatically subjects it to Joint Commission quality standards.

WakeMed has an excellent quality rating. The program will immediately participate in an existing Tumor Registry and Tumor Boards and WakeMed proposes to pursue American College of Surgeons Designation as a Community Cancer Program. All equipment will be new and radiation equipment will be subject to American College of Radiology accreditation.

...

All Radiation Oncologists will be board certified. Other staff members, including those provided by third party vendors, will be held to the highest levels of certification for their respective jobs. ...

...

WakeMed strives to provide high-quality services to all. Because the linear accelerator, simulator and radiation oncology program will be part of WakeMed Raleigh, the program will follow and maintain the same quality and performance improvement policies and programs already established at WakeMed.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 152-153, the applicant states:

“..., WakeMed plans to serve a high proportion of Medicaid, Medicare, and Charity Care patients. As noted in Figure 5, WakeMed Tumor Registry history demonstrates access to medically underserved patients; 19 percent had no insurance, or prescription coverage only.

WakeMed has contract arrangements with three of the five North Carolina Medicaid managed care plans; and it is working on arrangements with the other two. Proformas assume that legislation related to North Carolina Medicaid Expansion and activities related to HASP will be in place by the first project year. This will increase Medicaid eligibles. ...

...

..., *WakeMed facilities do not discriminate against any patient based on income, age, gender, ethnicity, physical [disability], ability to pay, or insurance coverage. ...*

...

WakeMed has a long history of working with Advance Community Health Center locations throughout Wake, Franklin, and Harnett County to meet the specialty care needs of people who rely on Advance for their primary care. Advance is a Federally Qualified Health Center whose mission is to address the health needs of medically underserved communities. Through its partnership with Advance and with other county institutions like Urban Ministries, WakeMed [stays] directly connected with geographic and informally organized hot spots where residents may be at risk of chronic disease. WakeMed's Population Health Program proactively works with these partnerships, to improve the health status of the medically underserved and all residents."

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 84, the applicant states:

“This project creates a new radiation oncology facility in an underserved part of the county, significantly increasing patient choice and competition, particularly for patients in Garner and the southeastern part of Wake County.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 84, the applicant states:

“The proposed facility will have lower average reimbursement for Medicare patients than on-campus hospital facilities. Creating a new site of service also reduces transportation barriers and increases patients for convenience, decreasing the time they may need to take away from work for treatment.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 84, the applicant states:

“Patients will have access to high-quality state-of-the-art services for which Duke is renowned in a new location. This will also improve coordination of care for patients seeking other services within the Duke Health system, including other services within the Duke Cancer Institute.

DUHS is committed to delivering high-quality care at all of its facilities, and will continue to maintain the highest standards and quality of care, consistent with the standards that DUHS has sustained throughout its illustrious history of providing patient care.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 85, the applicant states:

“DUHS will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. Duke’s financial assistance policy will apply to these services. This facility will also bring critical oncology services to a new geographic area, which will lower transportation and other barriers to care.”

See also Sections C and L of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness because the applicant did not adequately demonstrate: a) the need the population to be served has for the proposal or that projected utilization is based on reasonable and adequately supported assumptions; b) that projected revenues and operating costs are reasonable; and c) that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussions regarding demonstration of need and projected utilization, projected revenues and operating costs, and unnecessary duplication found in Criterion (3), Criterion (5), and Criterion (6), respectively, are incorporated herein by reference. A proposal that cannot demonstrate need, cannot demonstrate that projected revenues and operating costs are based on reasonable and adequately supported assumptions, and cannot demonstrate that the proposed project is not an unnecessary duplication cannot have a positive impact on cost-effectiveness.

Conclusion – The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described 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 – All Applications

Project ID #J-12371-23/UNC Rex Hospital/Acquire one LINAC

The applicant proposes to acquire and add an additional LINAC at UNC Health Rex Cancer Care of Wakefield (UNC Rex Wakefield).

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 10 hospitals with LINACs and three freestanding facilities with existing and operational LINACs located in North Carolina.

In Section O, pages 123-125, the applicant states that during the 18 months immediately preceding the submittal of the application there were two incidents each at two separate hospitals resulting in findings of immediate jeopardy out of the 10 hospitals identified in Form O. The applicant states all incidents of immediate jeopardy were adequately responded to and all termination notices withdrawn. The applicant provides supporting documentation in Exhibits O.4-2 and O.4-3. The applicant further describes an incident related to quality of care that did not result in a finding of immediate jeopardy at an additional hospital. The applicant

states that the incident was appropriately resolved and provides supporting documentation in Exhibit O.4-1. After reviewing and considering information provided by the applicant and considering the quality of care provided at all 10 hospitals and three freestanding facilities with LINACs, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12376-23/WakeMed Raleigh Medical Park/Acquire one LINAC

The applicant proposes to acquire a fixed LINAC and a CT simulator to be located at WakeMed Raleigh Medical Park (WakeMed RMP), a medical office building that will be located adjacent to WakeMed Raleigh Campus.

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. There are no facilities owned, operated, or managed by WakeMed or a related entity that have a LINAC and are located in North Carolina.

In Section O, page 163, the applicant states that during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy that occurred at WakeMed. After reviewing and considering information provided by the applicant and considering the quality of care provided at WakeMed, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

Project ID #J-12379-23/Duke Radiation Oncology Garner/Acquire one LINAC

The applicant proposes to acquire a LINAC and CT simulator to develop Duke Garner, a new radiation oncology facility licensed under Duke Raleigh Hospital.

On Form O in Section Q, the applicant identifies the facilities with LINACs located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 3 hospitals with LINACs and one freestanding facility with an approved but not yet developed LINAC located in North Carolina. Additionally, Duke LifePoint, a joint venture that the applicant is involved with, has four additional hospitals with LINACs in North Carolina.

In Section O, pages 87-88, the applicant states that during the 18 months immediately preceding the submittal of the application there were two separate incidents at the same facility resulting in findings of immediate jeopardy. The applicant states that the facility was back in compliance after the first incident. The second incident happened approximately one month prior to the submission of this application. The applicant states the facility has submitted an action plan, had a follow up survey, and is now awaiting a formal response. After reviewing and considering information provided by the applicant and considering the quality of care provided at all seven hospitals with existing LINACs, 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.

G.S. 131E-183 (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.

**NC – UNC Rex Hospital, Duke Radiation Oncology Garner
C – WakeMed Raleigh Medical Park**

SECTION .1900 - CRITERIA AND STANDARDS FOR RADIATION THERAPY EQUIPMENT are applicable to all projects. The specific criteria are discussed below.

10A NCAC 14C .1903 PERFORMANCE STANDARDS

An applicant proposing to acquire a LINAC pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

(1) *identify the existing LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;*

-C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant identifies the existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

-NA- **WakeMed RMP.** There are no existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.

-C- **Duke Garner.** In Section Q, the applicant identifies the existing LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

(2) *identify the approved LINACs owned or operated by the applicant or a related entity and located in the proposed LINAC service area;*

-C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant identifies the approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

-NA- **WakeMed RMP.** There are no approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.

-C- **Duke Garner.** In Section Q, the applicant identifies the approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20.

- (3) *provide projected utilization of the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC during each of the first three full fiscal years of operation following completion of the project;*
- C- **UNC Rex Wakefield.** On Forms C.2a and C.2b in Section Q, the applicant provides projected utilization of all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - NA- **WakeMed RMP.** There are no existing or approved LINACs owned or operated by the applicant or a related entity and located in Service Area 20. Therefore, this Rule is not applicable to this review.
 - C- **Duke Garner.** In Section Q, the applicant provides projected utilization of all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (4) *provide the assumptions and methodology used for the projected utilization required by Item (3) of this Rule;*
- C- **UNC Rex Wakefield.** In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - C- **WakeMed RMP.** In the Form C Utilization – Assumptions and Methodology subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - C- **Duke Garner.** In the Assumptions – Form C subsection of Section Q, the applicant provides the assumptions and methodology used to project utilization for all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (5) *project that the LINACs identified in Items (1) and (2) of this Rule and the proposed LINAC shall perform during the third full fiscal year of operation following completion of the project either:*
- (a) *6,750 or more ESTVs per LINAC; or*

(b) *serve 250 or more patients per LINAC.*

- NC- **UNC Rex Wakefield.** On Form C.2b in Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. However, projected utilization is not reasonable and adequately supported. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

- C- **WakeMed RMP.** On Form C.2b in Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- NC- **Duke Garner.** In Section Q, the applicant projected that all existing and approved LINACs owned or operated by the applicant or a related entity located in Service Area 20 and the proposed LINAC will serve 250 or more patients per LINAC. However, projected utilization is not reasonable and adequately supported. The discussion regarding need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, the application is not conforming to this Rule.

COMPARATIVE ANALYSIS FOR ACUTE CARE BEDS

Pursuant to G.S. 131E-183(a)(1) and the 2023 State Medical Facilities Plan, no more than one LINAC may be approved for Service Area 20 in this review. Because the applications in this review collectively propose to develop three LINACs in Service Area 20, all applications cannot be approved for the total number of beds proposed. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in the LINAC Comparative Analysis.

- Project ID #J-12371-23 / **UNC Rex Hospital** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination
- Project ID #J-12376-23 / **WakeMed Raleigh Medical Park** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination
- Project ID #J-12379-23 / **Duke Radiation Oncology Garner** / Acquire a new LINAC pursuant to the 2023 SMFP adjusted need determination

The analysis of comparative factors and what conclusions the Agency reaches (if any) regarding specific comparative analysis factors is determined in part by whether the applications included in the review provide data that can be compared and whether or not such a comparison would be of value in evaluating the competitive applications.

Conformity with Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved.

UNC Rex Hospital's application, **Project ID #J-12371-23**, and **Duke Radiation Oncology Garner's** application, **Project ID #J-12379-23**, are not conforming to all applicable statutory and regulatory review criteria. The application submitted by **WakeMed Raleigh Medical Park**, **Project ID #J-12376-23** is conforming to all applicable statutory and regulatory review criteria. Therefore, with regard to conformity with review criteria, the application submitted by **WakeMed Raleigh Medical Park** is a more effective alternative than the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner**.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

Each application proposes to provide radiation therapy services and CT simulation services. Therefore, regarding scope of services, all three applications are equally effective.

Geographic Accessibility

As of the date of this decision, there are 11 existing and approved LINACs in Service Area 20, as illustrated in the following table.

Location of Service Area 20 Existing/Approved LINACs	
Facility	Existing/Approved LINACs
Duke Green Level*	1
Duke Raleigh Hospital	2
Duke Women’s Cancer	1
UNC Rex Hospital	3
UNC Rex Wakefield	1
UNC Rex East Raleigh	1
UNC Panther Creek*	1
Service Area 20 Total	11

Sources: Table 17C-1, 2023 SMFP; applications under review; Agency records.

*LINAC approved for development or approved for relocation and not currently operational.

The following table illustrates where the existing and proposed LINACs are located or are proposed to be located within Service Area 20.

Facility	Total LINACs*	Address	Location
Duke Green Level	1	3208 Green Level W Road, Cary	Central Wake County
Duke Raleigh Hospital	2	3400 Wake Forest Road, Raleigh	Central Wake County
Duke Women’s Cancer	1	4101 Macon Pond Road, Raleigh	Central Wake County
Duke Radiation Oncology Garner	1	130 Timber Drive East, Garner	Southeast Wake County
UNC Rex Hospital	2	4420 Lake Boone Trail, Raleigh	Central Wake County
UNC Rex Wakefield	1	11200 Governor Manly Way, Raleigh	Northern Wake County
UNC Rex East Raleigh	1	117 Sunnybrook Road, Raleigh	Central Wake County
UNC Panther Creek**	1**	6715 McCrimmon Parkway, Cary	Eastern Wake County
UNC Rex Holly Springs**	1**	850 South Main Street, Holly Springs	Southern Wake County
WakeMed Raleigh Medical Park	1	25 Sunnybrook Road, Raleigh	Central Wake County

*If all requested LINACs could be approved

**After the beginning of the review for these applications, based on a material compliance approval, the new location for the LINAC that was previously going to be located at UNC Panther Creek is UNC Rex Holly Springs Hospital, 850 South Main Street in Holly Springs, which is located in southwest Wake County.

There are currently five facilities with existing and operational LINACs in Service Area 20.

UNC Rex Hospital proposes to add a second LINAC to UNC Rex Wakefield in northeast Raleigh/Wake County, where there is currently an existing and operational LINAC. **WakeMed Raleigh Medical Park** proposes to develop a LINAC adjacent to its campus in southeast Raleigh/southeast Wake County, where there is not currently an existing or approved LINAC. However, the proposed location is approximately half a mile away on the same road as an existing LINAC (UNC Rex East Raleigh). **Duke Radiation Oncology Garner** proposes to develop a LINAC in Garner, in southern Wake County, where there is not currently an existing or approved LINAC. Therefore, **Duke Radiation Oncology Garner** is the more effective alternative with regard to

geographic accessibility and **UNC Rex Hospital** and **WakeMed Raleigh Medical Park** are less effective alternatives.

Historical Utilization

The table below shows LINAC utilization for existing facilities as reported in Table 17C-1 of the 2023 SMFP. Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor.

Service Area 20 Historical Utilization - LINACs					
Facility	County	LINACs	# of Procedures /ESTVs	Average # of Procedures /ESTVs per LINAC	(Surplus) /Deficit
Duke Raleigh Hospital	Wake	4	21,075	5,269	(0.88)
UNC Rex Cancer Care of East Raleigh	Wake	1	5,148	5,148	(0.24)
UNC Rex Hospital (includes UNC Rex Wakefield)	Wake	4	21,639	5,410	(0.79)
Total		11	47,862	4,351	(3.91)

Sources: Table 17C-1, Table 17C-5 – 2023 SMFP

As shown in the table above, **UNC Rex Hospital** is the only existing facility applying to acquire a LINAC in Service Area 20. **Duke Radiation Oncology Garner** is not an existing facility and thus has no historical utilization, but its parent company has existing LINACs in Service Area 20. **WakeMed Raleigh Medical Park** is not an existing facility and thus has no historical utilization and does not have a parent company operating existing LINACs in Service Area 20.

Therefore, a comparison of historical utilization cannot be effectively evaluated.

Competition (Patient Access to a New or Alternate Provider)

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer acute care beds than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

As of the date of this decision, there are 11 existing and approved LINACs in Service Area 20. **UNC Rex Hospital** (via its parent company) currently controls 54.5% of the LINACs and **Duke Radiation Oncology Garner** (via its parent company) controls 45.5% of the LINACs in Service Area 20. **WakeMed Raleigh Medical Park** (via its parent company) does not have existing or approved LINACs in Service Area 20.

If **UNC Rex Hospital’s** application is approved, **UNC Rex Hospital** (via its parent company) would control 7 of the 12 existing and approved LINACs in Service Area 20, or 58.3% of the 12 existing and approved LINACs. If **Duke Radiation Oncology Garner’s** application is approved, **Duke Radiation Oncology Garner** (via its parent company) would control 5 of the 12 existing and approved LINACs in Service Area 20, or 41.7% of the 12 existing and approved LINACs. If **WakeMed Raleigh Medical Park’s** application is approved, **WakeMed Raleigh Medical Park** (via its parent company) would

control 1 of the 12 existing and approved LINACs in Service Area 20, or 8.3% of the 12 existing and approved LINACs.

Therefore, with regard to patient access to a new or alternate provider, the application submitted by **WakeMed Raleigh Medical Park** is the more effective alternative, and the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner** are less effective alternatives.

Access by Service Area Residents

In Chapter 17, page 311, the 2023 SMFP defines a LINAC’s service area as “...one of the 28 multicounty groupings described in the Assumptions of the Methodology.” Table 17C-4 on page 320 shows Service Area 20 is comprised of Franklin and Wake counties. Thus, the service area for this project consists of those two counties. Facilities may also serve residents of counties not included in their service area. Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for additional acute care beds in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Projected Service to Service Area 20 Residents (FY3)		
Applicant	# Service Area 20 Residents	% Service Area 20 Residents
UNC Rex Hospital	724	94.5%
WakeMed Raleigh Medical Park	344	77.8%
Duke Radiation Oncology Garner	151*	55.3%*

Sources: Project ID #J-12371-23 p.40, Project ID #J-12376-23 p.51, Project ID #J-12379-23 p.33

*Incomplete information; see discussion below

As shown in the table above, **UNC Rex Hospital** projects to serve both the highest number of Service Area 20 residents and the highest percentage of Service Area 20 residents.

However, **Duke Radiation Oncology Garner** projects utilization based on ZIP codes. At least four of the ZIP codes it uses in projecting patient origin extend beyond the Wake County line into other counties (27520, 27529, 27592, and 27603). There is not a way to identify which of the patients from those ZIP codes actually reside in Service Area 20 and which ones do not.

Considering the discussion above, the Agency believes that in this specific instance attempting to compare the applicants based on access to LINAC services for residents of Service Area 20 would be ineffective. Therefore, the result of this analysis is inconclusive.

Access by Underserved Groups

“Underserved groups” is defined in G.S. 131E-183(a)(13) as follows:

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with

disabilities], 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 access by underserved groups, the applications in this review are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for each facility using the following metrics: Total Medicare Revenue, Average Medicare Revenue per Patient, and Percentage of Gross Revenue.

Projected Medicare Revenue – 3rd Full FY			
Applicant	Total Medicare Rev.	Av. Medicare Rev./Patient	% Of Gross Rev.
UNC Rex Hospital	\$8,994,433	\$11,742	59.2%
WakeMed Raleigh Medical Park	\$10,464,283	\$23,675	50.6%
Duke Radiation Oncology Garner	\$7,074,886	\$25,915	47.9%

Sources: Forms C and F.2b for each applicant

As shown in the table above, **WakeMed Raleigh Medical Park** projects the highest total Medicare revenue, **Duke Radiation Oncology Garner** projects the highest average Medicare revenue per patient, and **UNC Rex Hospital** projects the highest Medicare revenue as a percentage of gross revenue. Generally, the application projecting to serve a larger number of Medicare patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicare patients, all three applications are equally effective alternatives.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for each facility using the following metrics: Total Medicaid Revenue, Average Medicaid Revenue per Patient, and Percentage of Gross Revenue.

Projected Medicaid Revenue – 3rd Full FY			
Applicant	Total Medicaid Rev.	Av. Medicaid Rev./Patient	% of Gross Rev.
UNC Rex Hospital	\$91,546	\$120	0.6%
WakeMed Raleigh Medical Park	\$968,152	\$2,190	4.7%
Duke Radiation Oncology Garner	\$981,086	\$3,594	6.6%

Sources: Forms C and F.2b for each applicant

As shown in the table above, **Duke Radiation Oncology Garner** projects the highest total Medicaid revenue, the highest average Medicaid revenue per patient, and the highest Medicaid revenue as a percentage of gross revenue. Generally, the application projecting to serve a larger number of Medicaid patients is the more effective alternative for this comparative factor. Therefore, regarding projected access for Medicaid patients, the application submitted by **Duke Radiation Oncology Garner** is a

more effective alternative and the applications submitted by **UNC Rex Hospital** and **WakeMed Raleigh Medical Park** are less effective alternatives.

Projected Average Net Revenue per Patient

The following table shows the projected average net revenue per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average net revenue per patient is the more effective alternative with regard to this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Patient – 3rd Full FY			
Applicant	Total # of Patients	Net Revenue	Av. Net Revenue/Patient
UNC Rex Hospital	766	\$6,515,126	\$8,505
WakeMed Raleigh Medical Park	442	\$6,698,020	\$15,154
Duke Radiation Oncology Garner	273	\$3,664,796	\$13,424

Sources: Forms C and F.2b for each applicant

As shown in the table above, **UNC Rex Hospital** projects the lowest average net revenue per patient in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **UNC Rex Hospital** is a more effective alternative and the applications submitted by **WakeMed Raleigh Medical Park** and **Duke Radiation Oncology Garner** are less effective alternatives.

Projected Average Operating Expense per Patient

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Projected Average Operating Expense per Patient – 3rd Full FY			
Applicant	Total # of Patients	Operating Expenses	Av. Operating Expense/Patient
UNC Rex Hospital	766	\$4,403,599	\$5,749
WakeMed Raleigh Medical Park	442	\$5,398,833	\$12,215
Duke Radiation Oncology Garner	273	\$5,971,791	\$21,875

Sources: Forms C and F.2b for each applicant

As shown in the table above, **UNC Rex Hospital** projects the lowest average operating expense per patient in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **UNC Rex Hospital** is a more effective alternative and the applications submitted by **WakeMed Raleigh Medical Park** and **Duke Radiation Oncology Garner** are less effective alternatives.

SUMMARY

The following table lists the comparative factors and states which application is the more effective alternative with regard to that particular comparative factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	UNC Rex Hospital	WakeMed Raleigh Medical Park	Duke Radiation Oncology Garner
Conformity with Review Criteria	Less Effective	More Effective	Less Effective
Scope of Services	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility	Less Effective	Less Effective	More Effective
Historical Utilization	Inconclusive	Inconclusive	Inconclusive
Competition/Access to New/Alternate Provider	Less Effective	More Effective	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive
Access by Underserved Groups			
Projected Medicare	Equally Effective	Equally Effective	Equally Effective
Projected Medicaid	Less Effective	Less Effective	More Effective
Projected Average Net Revenue per Patient	More Effective	Less Effective	Less Effective
Projected Average Operating Expense per Patient	More Effective	Less Effective	Less Effective

- With respect to Conformity with Review Criteria, **WakeMed Raleigh Medical Park** offers the more effective alternative. See Comparative Analysis for discussion.
- With respect to Geographic Accessibility, **Duke Radiation Oncology Garner** offers the more effective alternative. See Comparative Analysis for discussion.
- With respect to Competition/Access to New Provider, **WakeMed Raleigh Medical Park** offers the more effective alternative. See Comparative Analysis for discussion.
- With respect to Projected Medicaid Access, **Duke Radiation Oncology Garner** offers the more effective alternative. See Comparative Analysis for discussion.
- With respect to Projected Average Net Revenue per Patient, **UNC Rex Hospital** offers the more effective alternative. See Comparative Analysis for discussion.
- With respect to Projected Average Operating Expense per Patient, **UNC Rex Hospital** offers the more effective alternative. See Comparative Analysis for discussion.

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of acute care beds that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in LINACs in excess of the need determination for Service Area 20.

However, the applications submitted by **UNC Rex Hospital** and **Duke Radiation Oncology Garner** are not approvable and therefore cannot be considered an effective alternative. Consequently, the following applications are denied:

Project ID #J-12371-23 / **UNC Rex Hospital** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #J-12379-23 / **Duke Radiation Oncology Garner** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Based upon the independent review of each application and the Comparative Analysis, the following application is approved:

Project ID #J-12376-23 / **WakeMed Raleigh Medical Park** / Acquire one linear accelerator pursuant to the 2023 SMFP need determination

Project ID #J-12376-23, **WakeMed Raleigh Medical Park**, is approved subject to the following conditions.

1. **WakeMed (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one linear accelerator pursuant to the need determination in the 2023 SMFP.**
3. **The certificate holder shall acquire no more than one CT simulator.**
4. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on March 1, 2024.**
5. **The certificate holder 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.**
6. **The certificate holder 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.**

- 7. The certificate holder 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.**