

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 27, 2023

Findings Date: December 4, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Micheala Mitchell

Project ID #: J-12399-23

Facility: WakeMed North Hospital

FID #: 090441

County: Wake

Applicants: WakeMed

Project: Acquire a fixed MRI scanner pursuant to Policy TE-3

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.

C

WakeMed (hereinafter referred to as “the applicant”) proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2023 SMFP. Therefore, there are no need determinations applicable to this review.

Policies

Two policies in Chapter 4 of the 2023 SMFP is applicable to this application: *Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy TE-3

Policy TE-3 on page 28 of the 2023 SMFP states:

“The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital or a hospital campus: that has licensed acute care beds;

- 1. that provides emergency care coverage 24 hours a day, seven days a week.*
- 2. The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.*

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The proposed fixed MRI scanner:

- 1. must be located on the main campus of the hospital as defined in G.S. § 131E-176(14n); or*
- 2. must be located at another acute care hospital on a campus that operates under the main hospital’s license.*

The proposed fixed MRI scanner cannot be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.

The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.”

In Section B, pages 28-29, and in Exhibit B.19, the applicant explains why it believes its application is consistent with Policy TE-3. The applicant adequately demonstrates that WakeMed North is a facility with licensed acute care beds that provides an operational emergency department that is open 24 hours a day year-round, does not currently have an existing or approved MRI scanner at the WakeMed North Hospital location, and will perform at least 850 weighted MRI procedures during the third full operating year following completion. Additionally, WakeMed North is a campus of WakeMed that operates under WakeMed’s license.

Policy GEN-4

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 29-31, the applicant describes the project's plan to improve energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the proposal is consistent with Policy TE-3 and Policy GEN-4 based on the following:
 - WakeMed North is a facility with licensed acute care beds that provides an operational emergency department that is open 24 hours a day year-round.
 - WakeMed North Hospital is licensed under WakeMed's Raleigh license.
 - The applicant does not currently have an existing or approved MRI scanner at the WakeMed North Hospital location and will perform at least 850 weighted MRI procedures during the third full operating year following completion.
 - The applicant adequately documents that it has a plan in place to ensure water and energy conservation in the development of the proposed project.

(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.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

Patient Origin

On page 331, the 2023 SMFP defines the fixed MRI service area as “... the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”. Therefore, for the purpose of this review, the fixed MRI service area is Wake County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for MRI services for WakeMed North Hospital. Historical patient origin is based off mobile MRI services provided at WakeMed North Hospital for the last full fiscal year.

WakeMed North Hospital				
COUNTY	HISTORICAL MOBILE MRI SERVICES FY2022 (10/1/2021-09/30/2022)		THIRD FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION FY 2028 (10/1/2027-09/30/2028)	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
	Wake	1,505	74.03%	1,795
Franklin	269	13.23%	321	13.23%
Durham	64	3.15%	76	3.15%
Johnston	35	1.72%	42	1.72%
Vance	17	0.84%	20	0.84%
Granville	14	0.69%	17	0.69%
Nash	10	0.49%	12	0.49%
Wayne	9	0.44%	11	0.44%
Wilson	7	0.34%	8	0.34%
Other counties and Out of State	103	100.00%	2,425	100.00%
Total				

Source: Application pages 33 and 35.

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on the historical operating experience of WakeMed North Hospital. The applicant’s assumptions are reasonable and adequately supported because

they are based on the applicant's experience providing mobile MRI services to patients in the service area.

Analysis of Need

In Section C, on pages 36-40, the applicant summarized the proposal, stating it is based on multiple factors, as follows:

- ***Current Mobile MRI Capability is Outdated and Inadequate*** - *WakeMed North Hospital has utilized a mobile MRI scanner since 2006. The unit is outdated, produces lower quality images limiting the resolution and diagnostic capabilities for soft tissue scans. The unit cannot support any software upgrades to allow for additional coils, which limits the types of exams that can be offered.*
- ***Growth in Mobile MRI Volume at WakeMed North Hospital*** - *From FY 2020-2022, MRI procedures for emergency patients increased by over 100 percent, inpatient procedures increased 560 percent, observation procedures grew 505 percent, and outpatient procedures increased 50 percent.*
- ***Fixed MRI is a Standard of Care in Acute Care Hospitals*** - *Magnetic resonance imaging is an accepted and essential diagnostic imaging modality used in acute care hospitals and other clinical settings for medical diagnosis. It is particularly desirable because the procedures do not expose the body to harmful radiation.*
- ***Policy TE-3*** - *The development of Policy TE-3 and its inclusion in the annual SMFP is an acknowledgement that fixed MRI is a necessary diagnostic tool that should be available at any North Carolina acute care hospital that provides on-site emergency and surgical services.*

In Section C, pages 38-39, the applicant explains why it believes the future utilization projected for the proposed fixed MRI services supports the proposed services as summarized below:

- Since FY 2020, WakeMed North's total MRI volume on the mobile scanner has increased 185 percent, with significant growth in both inpatient and outpatient procedures. Growth in MRI volume is reflective of the growth in overall utilization at WakeMed North (page 38).
- Inpatient utilization at WakeMed North increased by over 75 percent, while emergency visits and observation cases increased by 28 percent and 63 percent, respectively. (page 39).
- From FY 2020-2022, MRI procedures for emergency patients increased by over 100 percent, inpatient procedures increased 560 percent, observation procedures grew 505 percent, and outpatient procedures increased 50 percent. (page 39).
- Projected FY 2023 volumes suggest a leveling out from FY 2022, as the current scanner cannot perform advanced MR studies and cannot be upgraded to perform cardiac, breast or neurological studies. Acquisition of a new fixed MRI scanner will enable

WakeMed North to offer a higher level of diagnostic imaging capabilities and capacity, to meet future utilization growth. (page 39).

Projected Utilization

In Section Q, Form C.2b, page 117, and Table Q.2, page 119, the applicant provides historical utilization for weighted MRI services at WakeMed North Hospital for fiscal years (FY 2021-2023), and projected utilization for MRI services through all three project years (FY 2026-2028), as illustrated in the following table:

WakeMed North Hospital - Historical and Projected Weighted MRI Utilization						
	HISTORICAL AND INTERIM WEIGHTED MRI UTILIZATION			Projected Weighted MRI Utilization		
	FY 2021	FY 2022	FY 2023	FY 2026	FY 2027	FY 2028
# Scanners	1	1	1	1	1	1
# Weighted MRI Scans	1,867	2,455	2,673	2,871	2,928	2,988

In Section Q, pages 119-123, “*Utilization Methodology and Assumptions*”, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- Step 1: The applicant compiled Mobile MRI Volume at WakeMed North Hospital. WakeMed North Hospital is currently served by a mobile MRI scanner six days a week. The applicant provided historic utilization of this mobile scanner for FY 2020 through FY 2023 (8 months annualized), for both unweighted and weighted procedures. (page 119)
- Step 2: The applicant calculated Historic Ratio of Outpatient to Inpatient Mobile MRI Scans FYs 2020-2023 (8 months annualized). (page 120)
- Step 3: The applicant calculated Historic Ratio of Inpatient MRI Scans Per Inpatient Discharge for FY 2020-2023 (8 months annualized) inpatient discharges (excluding normal newborns) (page 120)
- Step 4: To project WakeMed North’s Inpatient Discharges through the interim years and Project Year 3, WakeMed relied on population projections for Wake County from the N.C. Office of State Budget and Management. (pages 120-121)
- Step 5: The applicant projected Inpatient MRI Volume for project years 1-3 by using the projected inpatient discharges derived in Step 4 and applying a ratio of 0.0875 inpatient MRI scans to discharges calculated in Step 3. (page 121)
- Step 6: The applicant projected Outpatient MRI Volume by multiplying the ratio of outpatient-to-inpatient scans derived in Step 2 to projected inpatient scans calculated in Step 5. For the interim years and Project Years 1-3, the ratio of 3.30 was held constant and used to obtain outpatient MRI volume. (page 122)
- Step 7: The applicant projected Weighted MRI Scans by applying the outpatient and inpatient percentages to the total MRI scans calculated results in the following unweighted MRI volumes in the interim years and in Project Years 1-3. The applicant applied the projected weights to projected MRI volumes by calculating the weighted MRI scans in interim years through project year 3. WakeMed North Hospital is

projected to perform 2,988 weighted MRI procedures, well above the threshold of 850 weighted scans required by Policy TE-3. (pages 122-123)

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

- The applicant relied on its historical MRI utilization for both unweighted and weighted inpatient and outpatient MRI scans as the starting point for projecting future utilization.
- The applicant applied calculated ratios to project inpatient MRIs during the interim years and Project Years 1-3.
- The applicant relied on population growth projections from reliable sources to determine population growth in the service area.

Access to Medically Underserved Groups

In Section C, page 45, the applicant states:

“As a private, not-for-profit hospital system, WakeMed ensures access to health care services for all patients, regardless of income, payer status, gender, race, ethnicity, or physical handicap. WakeMed has long been committed to improving patient access.”

On pages 46-54 of the application, and Exhibit A.1, pages 1-16, Exhibit C.6.1, pages 22-24, Exhibit C.6.2, pages 25-31, and Exhibit L.4, the applicant provides summation and documentation of their non-discrimination practices and policies.

On page 55, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low-income persons	8.95%
Racial and ethnic minorities	31.9%
Women	68.4%
Persons 65 and older	34.2%
Medicare beneficiaries^	23.4%
Medicaid recipients^	16.8%

Source: Section C, page 55

^ Figures were rounded by the analyst

*The applicant states it does track 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 on the applicant’s policy.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant does not 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.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

In Section E, pages 65-66, 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:

- Status Quo: Continue to Rely on Mobile MRI to Serve North Hospital Patients - Maintaining the status quo would not only require WakeMed North Hospital to continue to operate without MRI services for one day each week, but it would also require higher acuity patients to continue to be transferred, which delays care and decreases provider and patient satisfaction.
- Transfer Patients Requiring MRI to Another Provider – Currently, many patients must be transferred to WakeMed Raleigh for imaging services, then remain for the duration of their care or, in some instances, are returned to WakeMed North to continue their treatment. In both cases, this causes delays in treatment, increases cost, and can cause capacity constraints at WakeMed Raleigh.
- Replace Mobile MRI with a New Mobile MRI and Continue to Serve WakeMed North - WakeMed evaluated the option of replacing the current mobile MRI scanner with a

new model which contained the features and capabilities to support the growing acuity at WakeMed North. However, this was not a viable option because there are still significant limitations on the types of patients that can be ambulated and served on a mobile MRI.

- Apply for a Fixed MRI Scanner in Response to SMFP Need Determination - WakeMed has not qualified to apply. Performance Standards in 10A NCAC 14C.2703(a) require that all MRIs owned by the applicant be utilized at full capacity, which is complicated on a mobile MRI which is required to move to different host sites.

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

- The applicant provides reasonable and adequately supported 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

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above. Therefore, the application 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 fixed MRI scanner pursuant Policy TE-3 to be located at WakeMed North Hospital.**
- 3. Upon completion of the project, WakeMed North Hospital shall have no more than one fixed MRI scanner.**
- 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 February 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 acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 124, the applicant projects the total capital cost of the project as shown in the table below.

Site Preparation	\$500,000
Construction/ Renovation Costs	\$9,472,176
Architect/ Engineering Fees	\$925,230
Medical Equipment	\$2,301,335
Non-Medical Equipment	\$90,000
Furniture	\$15,000
Consultant Fees	\$100,000
Other	\$365,719
Total	\$13,769,460

In Section Q, the applicant provides the assumptions used to project the capital cost. 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 provides an equipment quote for the proposed MRI scanner.
- In Exhibit K.3, the applicant provides a construction cost estimate signed by the project architect dated June 15, 2023, which includes a cost break down and which matches the construction cost listed on Form F.1a.

In Section F.3, page 68, the applicant states there will be no working capital costs because it is an existing facility currently offering mobile MRI services.

Availability of Funds

In Section F, page 67, the applicant states the capital cost will be funded through the accumulated reserves of WakeMed.

Exhibit F.2.1 contains a letter signed by the Senior Vice President and Chief Financial Officer for WakeMed, indicating the availability of funding.

Exhibit F.2-2 contains the most recent WakeMed audited financial statements documenting the availability of the necessary funds.

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

- The applicant provides documentation of WakeMed's commitment to use the necessary funding toward development of the proposed project.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital cost.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years (FY), October 1 to September 30, following project completion. The following table shows the projections for the MRI services:

WakeMed North Hospital			
	1ST FY	2ND FY	3RD FY
	10/1/25-09/30/26	10/1/26-09/30/27	10/1/27-09/30/28
# of Scans (Weighted)	2,871	2,928	2,988
Gross Revenue	\$15,288,767	\$15,983,874	\$16,720,087
Net Revenue	\$2,570,940	\$2,692,023	\$2,819,725
Average Net Revenue per Weighted MRI Scan	\$895.48	\$919.40	\$943.68
Operating Costs	\$1,425,727	\$1,843,473	\$1,885,908
Average Operating Costs per Weighted MRI Scan	\$496.59	\$629.60	\$631.16
Net Income	\$1,145,213	\$848,550	\$933,817

Source: Section Q, Form F.2b

The assumptions used by the applicant in preparation of the pro forma financial statements are provided 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 accounts for projected operating expenses and explains the revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of 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.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

On page 331, the 2023 SMFP defines the fixed MRI service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. Therefore, for the purpose of this review, the fixed MRI service area is Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Wake County service area, summarized from Table 17E-1, pages 350-351 of the 2023 SMFP:

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2022
Duke Raleigh Hospital (Duke University Health System)	2	13,139
Rex Hospital – Main (UNC Health System)	2	11,373
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0
WakeMed – New Bern Ave (WakeMed)	2	15,465
WakeMed Cary Hospital (WakeMed)	1	5,625
Cardinal Points Imaging of the Carolinas Midtown (Pinnacle)	1	5,912
Duke Health Arrington Radiology (Duke University Health System)	1	0
Duke Imaging Holly Springs (Duke University Health System)	1	1,938
Duke Imaging North Raleigh (Duke University Health System)	0	0
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,298
Raleigh Neurology Imaging, PLLC (Alliance)	1	5,586
Raleigh Radiology - Cary (Alliance)	1	7,146
Raleigh Radiology – Cedarhurst (Pinnacle)	1	7,106
The Bone and Joint Surgery Center (Bone & Joint)	1	2,208
Wake Radiology MRI (WR Imaging, LLC)	1	4,136
Wake Radiology Diagnostic Imaging (Alliance)	1	5,072
Wake Radiology MRI (WR Imaging, LLC)	1	3,867
Wake Radiology MRI (WR Imaging, LLC)	1	4,889
2023 SMFP Need Determination	1	--
Total	21	98,760

Source: 2023 SMFP, Table 17E-1, pages 350-351

In Section G, pages 75-76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Wake County. The applicant states:

“WakeMed North Hospital currently does not offer fixed MRI services. The proposed project will be developed pursuant to Policy TE-3 in the 2023 SMFP, which provides a mechanism for acute care hospitals without a fixed MRI to develop this service outside an SMFP need determination.”

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:

- The proposed project will be developed pursuant to Policy TE-3 in the 2023 SMFP which is based on the principle that a fixed MRI is a standard of care in an acute care hospital.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

In Section Q, Form H, page 130, the applicant provides projected full-time equivalent (FTE) positions for its MRI services, as illustrated in the following table:

POSITION	WAKEMED NORTH HOSPITAL PROJECTED STAFFING		
	1 ST FY FY 2026	2 ND FY FY 2027	3 RD FY FY 2028
MRI Technologist	5.80	5.80	5.80
MRI Technologist Assistant	2.70	2.70	2.70
Supervisor	.25	.25	.25
Total	8.75	8.75	8.75

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 77-83, and in Exhibit C.6.3, Exhibit H.3.1, Exhibit H.3.2, Exhibit H.3.3, Exhibit H.3.4, and Exhibit O.2.3, 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 currently operates a mobile MRI scanner at this location and has projected sufficient staff to operate the proposed fixed MRI scanner once it is operational.
- The applicant has experience staffing other WakeMed facilities that utilize one fixed MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

Ancillary and Support Services

In a table in Section I, page 84, and Exhibit I.1, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section I, pages 84-85 the applicant explains how each ancillary and support service is and will be available. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available because these services are currently provided for patients of WakeMed North Hospital and will continue to be after the proposed project is developed.

Coordination

In Section I, page 86, the applicant describes its existing and proposed relationships with other local health care and MRI providers and provides supporting documentation in Exhibit I.2.1, and Exhibit I.2.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant currently coordinates its services with the existing health care system and will continue to do so following the acquisition of the proposed fixed MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction

project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

In Section K, page 90, the applicant states that the project involves constructing 17,030 square feet of new space. Line drawings are provided in Exhibit K.1.

In Section K, pages 90-91, and Exhibit K.3, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal.

In Section K, page 91, 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. The applicant states they have set aside revenue to fund projects such as the one proposed in this application.

On pages 91-93, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 94 the applicant provides the historical payor mix during FY 2022 for its existing fixed MRI services at Atrium Locust, as shown in the table below:

WakeMed North Hospital HISTORICAL PAYOR MIX, FY 2022	
PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	8.95%
Charity Care	
Medicare	23.36%
Medicaid	16.76%
Insurance	45.07%
Other	5.85%
Total	100.0%

Source: Section L, page 94

In Section L, page 95, the applicant provides the following comparison:

WakeMed North Hospital	Percentage of Total Patients Served by the Facility during the Last Full FY	Percentage of the Population of the Service Area [^]
Female	64.8%	51.1%
Male	35.2%	48.9%
Unknown	<0.1%	N/A
64 and Younger	78.6%	87.4%
65 and Older	21.4%	12.6%
American Indian	0.2%	0.8%
Asian	1.8%	8.3%
Black or African-American	31.0%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	55.4%	67.1%
Other Race	8.9%	2.8%
Declined / Unavailable	2.6%	N/A

[^] The percentages can be found online using the United States Census Bureau's QuickFacts

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 96, the applicant states it has no such obligation.

In Section L, page 96, the applicant states that no patient civil rights equal access complaints have been filed against West Wake Imaging, LLC in the 18 months immediately preceding the application deadline.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 97, the applicant projects the following payor mix for WakeMed North Hospital as a whole, and also for fixed MRI services during the third full fiscal year of operation following completion of the project, as shown in the tables below:

WakeMed North Hospital Projected Payor Mix FY 2028	
PAYOR CATEGORY	% OF TOTAL PATIENTS SERVED
Self-Pay	8.95%
Medicare	23.36%
Medicaid	16.76%
Insurance	45.07%
Other	5.85%
Total	100.0%

Source: Application page 97

WakeMed North Hospital Fixed MRI Services Projected Payor Mix FY 2028	
PAYOR CATEGORY	% OF TOTAL PATIENTS SERVED
Self-Pay	5.68%
Medicare	34.71%
Medicaid	4.86%
Insurance	50.39%
Other	4.36%
Total	100.00%

Source: Application page 97

As shown in the first table above, during the third full fiscal year of operation, the applicant projects that 8.95% of total services provided by WakeMed North Hospital will be provided to self-pay patients, 23.36% and 16.76% of total services will be provided to Medicare and Medicaid patients, respectively.

Additionally, during the third full fiscal year of operation, the applicant projects that 5.68% of fixed MRI services provided by WakeMed North Hospital will be provided to self-pay patients, 34.71% and 4.86% of total fixed MRI services will be provided to Medicare and Medicaid patients, respectively.

On page 97, the applicant provides the assumptions used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix for all of WakeMed North Hospital services and mobile MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 99, and Exhibit L.4, describes the means by which a person will have access to the proposed additional fixed MRI services at WakeMed North Hospital.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

In Section M, pages 100-102, 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, and Exhibit H.3.4. The applicant adequately demonstrates that health professional training programs in the area have and will continue to have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

C

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

On page 331, the 2023 SMFP defines the fixed MRI service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. Therefore, for the purpose of this review, the fixed MRI service area is Wake County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Wake County service area, summarized from Table 17E-1, pages 350-351 of the 2023 SMFP:

Facility (Owner)	# of Fixed MRI Scanners	Total Weighted Procedures Performed during Federal Fiscal Year (FFY) 2022
Duke Raleigh Hospital (Duke University Health System)	2	13,139
Rex Hospital – Main (UNC Health System)	2	11,373
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0
WakeMed – New Bern Ave (WakeMed)	2	15,465
WakeMed Cary Hospital (WakeMed)	1	5,625
Cardinal Points Imaging of the Carolinas Midtown (Pinnacle)	1	5,912
Duke Health Arrington Radiology (Duke University Health System)	1	0
Duke Imaging Holly Springs (Duke University Health System)	1	1,938
Duke Imaging North Raleigh (Duke University Health System)	0	0
Raleigh Neurology Associates (Raleigh Neurology Associates)	1	5,298
Raleigh Neurology Imaging, PLLC (Alliance)	1	5,586
Raleigh Radiology - Cary (Alliance)	1	7,146
Raleigh Radiology – Cedarhurst (Pinnacle)	1	7,106
The Bone and Joint Surgery Center (Bone & Joint)	1	2,208
Wake Radiology MRI (WR Imaging, LLC)	1	4,136
Wake Radiology Diagnostic Imaging (Alliance)	1	5,072
Wake Radiology MRI (WR Imaging, LLC)	1	3,867
Wake Radiology MRI (WR Imaging, LLC)	1	4,889
2023 SMFP Need Determination	1	--
Total	21	98,760

Source: 2023 SMFP, Table 17E-1, pages 350-351

Regarding the expected effects of the proposal on competition in the service area, the applicant references their comments in Section N, page 103, the applicant states:

“Development of a fixed MRI scanner at WakeMed North Hospital will enhance competition in Wake County. Currently, WakeMed North is the only acute care hospital in the county that does not provide fixed MRI services.”

Regarding the expected effects of the proposal on cost effectiveness, Section N, page 103, the applicant states:

“WakeMed proposes to acquire one fixed MRI scanner, pursuant to Policy TE-3 in the 2023 SMFP. Adding this service also will enable WakeMed North to serve patients more efficiently, eliminating the need for expensive patient transfers for a standard of care in imaging.”

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

Regarding the expected effects of the proposal on quality in the service area, Section N, page 104, the applicant states:

“WakeMed seeks to promote patient safety and enhance the quality in the delivery of healthcare services at WakeMed North. The proposal in this application will offer additional capacity to expand its surgical services while complementing its reputation

for high quality care. As part of the WakeMed system, WakeMed North strictly adheres to the system-wide quality assurance and performance improvement programs developed by WakeMed.”

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

Regarding the expected effects of the proposal on access by medically underserved groups in the service area, the applicant references their comments in Section N, pages 104-105, Exhibit N.2, Exhibit C.6.3, and Exhibit L.4, the applicant states:

“One of the central tenets of the Certificate of Need Statute is to ensure access to health care services to underserved groups, through a combination of location and capacity. Facilities that experience capacity issues, for inpatient and/or outpatient services, cannot adequately provide timely access to services. The proposed project will increase access to MRI services at WakeMed North, where both utilization and patient acuity have been increasing and the need for advanced imaging modalities has been more pronounced. Moreover, WakeMed North’s proposed service area is rapidly growing and aging. By increasing its imaging services capabilities, WakeMed North will ensure adequate access to the communities it serves.”

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 and the applicant’s record of providing quality care in the past.
- 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

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

The applicant proposes to acquire one fixed MRI scanner pursuant to Policy TE-3 to be located at WakeMed North Hospital in Raleigh, Wake County. Upon project completion, WakeMed North Hospital will operate one fixed MRI scanner, and one mobile MRI scanner.

In Section Q Form O, the applicant identifies the health service facilities located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of two hospitals, located in North Carolina.

In Section O, page 112, and Exhibit O.4, the applicant provides correspondence from Donald Gintzig, President and CEO of WakeMed, attesting that each of the WakeMed facilities listed in Section Q Form O Facilities have provided quality care during the 18 months immediately preceding the submission of this application.

After reviewing and considering information provided by the applicant, the Agency determines that 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.

NA

The applicant is submitting this application to obtain a fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP, which states:

“To qualify, the health service facility proposing to acquire the fixed MRI scanner shall demonstrate in its certificate of need application that it is a licensed North Carolina acute care hospital with emergency care coverage 24 hours a day, seven days a week and that does [sic] not currently have an existing or approved fixed MRI scanner as reflected in the inventory in the applicable State Medical Facilities Plan.

The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.

The performance standards in 10A NCAC 14C .2703 would not be applicable.

The fixed MRI scanner must be located on the hospital's 'main campus' as defined in G.S. 131E-176(14n)a [sic]."

The applicant is proposing to add a fixed MRI scanner at WakeMed North Hospital pursuant to Policy TE-3. The discussion regarding conformity with Policy TE-3 found in Criterion (1) is incorporated herein by reference. There are no administrative rules that are applicable to this proposal. Therefore, this criterion is not applicable.