

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: Tanya M. Saporito

Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: J-12393-23
Facility: Raleigh Radiology Knightdale
FID #: 190281
County: Wake
Applicant: Raleigh Radiology, LLC
Project: Acquire a fixed MRI scanner pursuant to the 2023 SMFP need determination

Project ID #: J-12395-23
Facility: Duke Imaging Garner
FID #: 230129
County: Wake
Applicant: Duke University Health System, Inc.
Project: Acquire a fixed MRI scanner pursuant to the 2023 SMFP need determination

Project ID #: J-12396-23
Facility: Wake Radiology Cary
FID #: 001330
County: Wake
Applicant(s): Wake Radiology Diagnostic Imaging, Inc.
WR Imaging, LLC
Project: Acquire a fixed MRI scanner 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 (CON Section) 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.

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-All Applications

Need Determination

The 2023 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for additional fixed MRI scanners in North Carolina by service area. Application of the need methodology in the 2023 SMFP identified a need for one fixed MRI scanner in the Wake County fixed MRI scanner service area. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed MRI scanner, for a total of three fixed MRI scanners. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

Policies

One policy in Chapter 4 of the 2023 SMFP is applicable to all three applications received in response to the need determination: *Policy GEN-3: Basic Principles*. Additionally, one policy in the 2023 SMFP is applicable to one application: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* is applicable to Project ID #J-12395-23, Duke University Health System, Inc.'s proposal to acquire one fixed MRI scanner in Wake County.

Policy GEN-3

Policy GEN-3 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.”

J-12393-23 / Raleigh Radiology, LLC / Acquire one fixed MRI scanner

Raleigh Radiology, LLC, hereinafter referred to as “the applicant”, or Raleigh Radiology, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located at its existing diagnostic center, Raleigh Radiology Knightdale in Knightdale, in Wake County. The applicant currently provides mobile MRI services at the Knightdale location through a contract with a third party vendor. The applicant proposes to replace the mobile MRI services with the fixed MRI scanner proposed in this application. On April 28, 2020 the applicant was approved to develop one fixed MRI scanner at its Cary location, Raleigh Radiology Cary, pursuant to the need determination in the 2019 SMFP. The applicant was issued a certificate of need for that fixed MRI scanner on October 15, 2023. Neither the applicant nor any related entities otherwise owns or operates any other fixed MRI scanners in Wake County.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Wake County fixed MRI scanner service area.

Policy GEN-3. In Section B, pages 26-29, the applicant provides information to show its application is conforming to Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 following reasons:

- The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
 - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

Duke University Health System, Inc., hereinafter referred to as “the applicant”, or DUHS, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located at a diagnostic center, Duke Imaging Garner, in Wake County. On June 6, 2023 the applicant was approved pursuant to CON Project ID #J-12328-23 to develop Duke Imaging Garner with mammography and ultrasound equipment. In this application, the applicant proposes a change of scope to Project ID #J-12328-23 and proposes to acquire a fixed MRI scanner pursuant to the need determination in the 2023 SMFP for one fixed MRI scanner in the Wake County fixed MRI scanner service area. The applicant currently owns and operates three fixed MRI scanners in Wake County and has been approved pursuant to CON Project ID #J-12073-21 to operate a fourth fixed MRI scanner in Wake County. That project is currently under appeal. Upon completion of this project, and assuming it will be awarded a certificate of need for the fixed MRI scanner proposed in Project ID #J-12073-21, the applicant will own and operate a total of six fixed MRI scanners in Wake County, one of which will be located at Duke Imaging Garner, along with one unit each of mammography and ultrasound.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Wake County fixed MRI service area.

Policy GEN-3. In Section B, pages 26-27, the applicant the applicant provides information to show its application is conforming to Policy GEN-3.

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.”

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 27-28, the applicant provides a written statement describing the project's plan to assure improved energy efficiency and water conservation. The applicant states it will ensure the facility and the proposed fixed MRI service will be designed and developed in compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption. The applicant provides supporting documentation in Exhibit F.1(a).

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

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 does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
 - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- The applicant adequately demonstrates the proposal is consistent with Policy GEN-4 based on its representations that the project includes a plan for energy efficiency and water conservation.

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC, hereinafter collectively referred to as "the applicant", or Wake Radiology Imaging, is an existing diagnostic imaging practice with several locations in Wake County. The applicant proposes to acquire one fixed

MRI scanner to be developed at Wake Radiology Cary. On pages 31-32 of the application, the applicant states it currently operates two fixed MRI scanners at its Wake Radiology Raleigh location. The applicant also owns and operates two mobile MRI scanners. The applicant states it contracts with Alliance Imaging through a services agreement for two freestanding fixed MRI scanners located at Wake Radiology Cary and Wake Radiology Garner. The applicant also partners with UNC Health Rex. Together, the applicant and UNC Health Rex operate three hospital-based fixed MRI scanners, two at UNC Health Rex Hospital in Raleigh and one that it states is approved to be relocated to the UNC Holly Springs hospital. Combined, the applicant and UNC Health Rex currently own or operate a total of five fixed MRI scanners in Wake County.

Need Determination. The applicant does not propose to develop more fixed MRI scanners than are determined to be needed in the Wake County fixed MRI scanner service area.

Policy GEN-3. In Section B, pages 27-30, the applicant the applicant provides information to show its application is conforming to Policy GEN-3.

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 does not propose to develop more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of MRI services in the service area;
 - The applicant adequately documents how the project will promote equitable access to MRI services in the service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

- (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
All Applications

J-12393-23 / Raleigh Radiology, LLC / Acquire one fixed MRI scanner

Raleigh Radiology LLC proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 to be installed in an existing diagnostic center, Raleigh Radiology Knightdale, in Knightdale.

Patient Origin

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1*”. In Chapter 5, page 32, the 2023 SMFP defines the service area for Acute Care Beds as “*...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” In Figure 5.1 on page 36 of the 2023 SMFP, Wake County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner at an existing diagnostic center in Knightdale in Wake County. Therefore, for the purpose of this review, the fixed MRI scanner service area is Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 41, the applicant states it does not currently own or operate any fixed MRI scanners in Wake County. The applicant was approved pursuant to Project ID #J-11825-19 to develop a fixed MRI scanner at its Cary location, but that project was under appeal and the certificate of need was issued October 15, 2023. Thus, the fixed MRI scanner approved for the Cary location is not yet operational.

The applicant states on page 41 that it currently provides mobile MRI services at the Knightdale location, and provides historical patient origin for the mobile MRI services. The following table from page 42 illustrates historical patient origin for existing mobile MRI services at Raleigh Radiology Knightdale for the last full fiscal year (FY), calendar year (CY) 2022:

**Raleigh Radiology Knightdale Mobile MRI Services
 Historical Patient Origin – CY 2022**

ZIP CODE/CITY	CY 2022	
	# PTS.	% OF TOTAL
27545 Knightdale	387	16.4%
27597 Zebulon	374	15.8%
27591 Wendell	338	14.3%
27610 Raleigh	182	7.7%
27616 Raleigh	102	4.3%
27604 Raleigh	120	5.1%
27571 Rolesville	74	3.1%
27615 Raleigh	21	0.9%
27614 Raleigh	34	1.4%
27587 Wake Forest	36	1.5%
27527 Clayton	59	2.5%
27557 Middlesex	25	1.1%
27520 Clayton	19	0.8%
27529 Garner	17	0.7%
27882 Spring Hope	32	1.4%
27549 Louisburg	61	2.6%
27596 Youngsville	19	0.8%
27856 Nashville	17	0.7%
27807 Bailey	11	0.5%
27577 Smithfield	9	0.4%
27576 Selma	11	0.5%
27896 Wilson	12	0.5%
27893 Wilson	29	1.2%
Remainder of NC	366	15.5%
Other States	11	0.5%
Total	2,366	100.0%

Percentages may not sum due to rounding.

The following table from page 43 illustrates historical patient origin for existing diagnostic imaging services, which includes bone density, CT, mammography, ultrasound and x-ray at Raleigh Radiology Knightdale for the last full fiscal year (FY), calendar year (CY) 2022:

**Raleigh Radiology Knightdale Diagnostic Imaging Services
 Historical Patient Origin – CY 2022**

COUNTY	CY 2022	
	# PTS.	% OF TOTAL
Wake	10,595	85.0%
Franklin	210	1.7%
Johnston	398	3.2%
Nash	715	5.7%
Wilson	165	1.3%
All other NC counties	351	2.8%
Other states	37	0.3%
Total	12,471	100.0%

Percentages may not sum due to rounding.

The following tables from pages 45-47 illustrate projected patient origin for the proposed fixed MRI services and for all imaging services, respectively, at Raleigh Radiology Knightdale for the first three full FYs, CYs 2025-2027:

Raleigh Radiology Knightdale Projected Patient Origin – Fixed MRI Services, CYs 2025-2027

ZIP CODE/CITY/COUNTY	1 ST FULL FY (CY 2025)		2 ND FULL FY (CY 2026)		3 RD FULL FY (CY 2027)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
27545 Knightdale, Wake County	517	11.3%	523	11.3%	528	11.4%
27597 Zebulon, Wake County	441	9.6%	446	9.7%	450	9.7%
27591 Wendell, Wake County	456	9.9%	460	10.0%	464	10.0%
27610 Raleigh, Wake County	728	15.9%	731	15.8%	735	15.8%
27604 Raleigh, Wake County	372	8.1%	374	8.1%	376	8.1%
27616 Raleigh, Wake County	459	10.0%	460	10.0%	462	9.9%
27527 Clayton, Johnston County	130	2.8%	131	2.8%	132	2.8%
27520 Clayton, Johnston County	134	2.9%	134	2.9%	135	2.9%
27529 Garner, Wake County	110	2.4%	110	2.4%	111	2.4%
27549 Louisburg, Franklin County	42	0.9%	42	0.9%	42	0.9%
27557 Middlesex, Nash County	76	1.6%	77	1.7%	78	1.7%
27615 Raleigh, Wake County	137	3.0%	137	3.0%	138	3.0%
27614 Raleigh, Wake County	78	1.7%	78	1.7%	79	1.7%
27571 Rolesville, Wake County	28	0.6%	29	0.6%	29	0.6%
27882 Spring Hope, Nash County	44	1.0%	45	1.0%	45	1.0%
27587 Wake Forest, Wake County	185	4.0%	186	4.0%	187	4.0%
27807 Bailey, Nash County	28	0.6%	28	0.6%	29	0.6%
27856 Nashville, Nash County	27	0.6%	28	0.6%	28	0.6%
27576 Selma, Johnston County	25	0.5%	25	0.5%	25	0.5%
27577 Smithfield, Johnston County	49	1.1%	50	1.1%	50	1.1%
27893 Wilson, Wilson County	18	0.4%	19	0.4%	19	0.4%
27896 Wilson, Wilson County	15	0.3%	15	0.3%	15	0.3%
27596 Youngsville, Franklin County	36	0.8%	36	0.8%	36	0.8%
Remainder of NC*	440	9.6%	440	9.5%	440	9.5%
Other States	11	0.2%	11	0.2%	11	0.2%
Total	4,587	100.0%	4,615	100.0%	4,644	100.0%

Percentages may not sum due to rounding.

*On application page 46 the applicant states "Remainder of NC" includes the remaining ZIP codes in Wake, Johnston, Nash, Franklin and Wilson counties and all other NC counties.

Raleigh Radiology Knightdale Diagnostic Imaging Services* Projected Patient Origin – CYs 2025-2027

COUNTY	CY 2025		CY 2026		CY 2027	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Wake	11,479	85.3%	11,711	85.5%	11,948	85.6%
Franklin	203	1.5%	209	1.5%	216	1.5%
Johnston	365	2.7%	374	2.7%	383	2.7%
Nash	708	5.3%	708	5.2%	708	5.1%
Wilson	254	1.9%	253	1.8%	252	1.8%
Remainder of NC	403	3.0%	407	3.0%	411	2.9%
Other states	37	0.3%	37	0.3%	37	0.3%
Total	13,449	100.0%	13,699	100.0%	13,954	100.0%

Percentages may not sum due to rounding.

*Does not include MRI patients

In Section C, page 44 and in Section Q, the applicant states projected patient origin for the proposed fixed MRI services are based on Raleigh Radiology’s historical experience providing mobile MRI services. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical experience providing mobile MRI services.

Analysis of Need

In Section C.4, pages 49-67, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- There is a need in the 2023 SMFP for one fixed MRI scanner in the Wake County fixed MRI scanner service area.
- There is increasing demand for MRI services at Raleigh Radiology Knightdale, despite the availability of mobile MRI services at that location.
- The location and availability of MRI scanners in Wake County indicates a need for MRI services in the Knightdale area. Utilizing data from the 2023 SMFP and the Registration and Inventory of Medical Equipment forms, the applicant identified and located all existing fixed and mobile MRI scanners in Wake County and mapped the locations of those scanners relative to the projected population of Wake County in 2028. The applicant applied a “grid system” to the Wake County map to identify potential voids in access to MRI services in the county and determined that the grid within which Raleigh Radiology Knightdale is located is only served by a mobile MRI scanner with limited service. The applicant states that the area proposed to be served by its proposed MRI scanner in eastern Wake County has a combined population of approximately 275,000 and the least access to MRI services compared to the remainder of the county. See the tables that illustrate the data on application pages 53-54.
- Population growth and aging in Wake County – The applicant examined Claritas data that shows the Wake County population as a whole is projected to increase from 2023-2028, and the ZIP codes projected to be served by Raleigh Radiology Knightdale are

projected to comprise over 20% of Wake County's total population growth during that time. The Claritas data utilized by the applicant also shows the 65 + population in the ZIP codes in the applicant's primary service area will comprise approximately 46% of the total population in these ZIP codes by 2028, thereby indicating a need for additional MRI services in the area. Older population groups are more likely to need MRI services than younger cohorts. See the tables that illustrate the data on application pages 56-57.

- Increasing MRI use rates in the state as a whole have increased steadily since FY 2017, which indicates a need for additional MRI services. The applicant states that MRI imaging is ideal for imaging all types of tissue, is non-invasive and emits no radiation, making it an increasingly desirable imaging tool for physicians. See the table that illustrates the data on application page 57.
- Community access to MRI services by Raleigh Radiology in the Raleigh Radiology Knightdale service area – The applicant states cost concerns, Wake County traffic congestion issues and referring physician interest in MRI services combine to make Raleigh Radiology and the Knightdale location an accessible choice for providing MRI services to the community.
- Social determinants of health that affect the increasing need for MRI services in the Raleigh Radiology Knightdale service area, such as disease incidence, obesity, poverty, and low education levels are prevalent in the county and are factors that contribute to the overall health risk status of a community. The applicant cites data that shows the risk factors for poorer overall health are higher in the proposed service area than in the county as a whole. The availability of additional MRI services in the service area will help diagnose and treat health conditions the service area is likely to experience, such as heart disease, cancer, liver disease and musculoskeletal problems.

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

- The 2023 SMFP identifies the need for one additional fixed MRI scanner in the Wake fixed MRI scanner service area.
- The applicant provides information and data to support its assertions regarding service area population growth and aging, as well as disease risk factors and the relative lack of MRI services in the service area.
- The applicant provides reliable information to support the need for fixed MRI services to serve its patient base more effectively and efficiently.

Projected Utilization

In Section Q, Form C.2b, the applicant provides projected utilization of the proposed fixed MRI scanner, as illustrated in the following table:

Projected MRI Utilization, First Three Project Years

	PARTIAL FY 10/1/24-12/31/24	1 ST FULL FY CY 2025	2 ND FULL FY CY 2026	3 RD FULL FY CY 2027
Number of Units	1	1	1	1
# Procedures (unweighted)	1,415	5,695	5,730	5,766
# Weighted Procedures	1,504	6,054	6,091	6,130

In Section Q, pages 134-156, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI scanner, as summarized below:

Step 1: Determine target service area population to be served by the MRI scanner – The 2023 SMFP defines the service area as Wake County, and the applicant proposed a service area of 23 ZIP codes in eastern Wake County and the adjacent counties of Franklin, Johnston, Nash and Wilson, based on its historical mobile MRI patients. The applicant identified a primary, secondary and tertiary service area based on those 23 ZIP codes. The applicant utilized Claritas population data for 2023 and 2028 and calculated a compound annual population growth rate (CAGR) for each of the service areas of 1.3% in the primary service area, 1.5% in the secondary service area and 0.7% in the tertiary service area. The applicant then calculated an overall CAGR of 1.3% for the entire 23 ZIP code service area. The applicant interpolated data for the years 2024-2027. See the tables on pages 136-137 that illustrate those calculations.

Step 2: Estimate the statewide MRI use rate per 1,000 population – Utilizing data from the North Carolina Office of State Budget and Management (NCOSBM) and the 2019-2023 SFMPs, the applicant calculated a statewide MRI use rate of 88.54 procedures per 1,000 population. The applicant states MRI utilization increased each year, notwithstanding the anomalous time during the COVID-19 pandemic when use rates were lower. The applicant elected to use a five-year state-wide MRI use rate, stating it is conservative given the steady increase in MRI utilization and the high growth of older population cohorts in Wake County. See the table on page 138 that illustrates those use rates per 1,000 population.

Step 3: Estimate the number of unadjusted MRI scans needed in the proposed service area in the years 2023-2028 – The applicant applied the MRI use rate calculated in Step 2 to the population estimates derived in Step 1 to determine the number of unadjusted MRI scans that would be needed in its total service area and in each of the primary, secondary and tertiary service areas. See the tables that illustrate the calculations on page 139 of the application.

Step 4: Estimate the five-year statewide average MRI weighting factor – Relying on Table 17E-1 in the 2023 SMFP, the applicant examined MRI utilization of unweighted and weighted MRI scans in the state and calculated a weighting ratio of 1.19 based on that data. See the table on page 140 that illustrates those calculations.

Step 5: Estimate the number of adjusted MRI scans needed in the proposed service area 2023-2028 – The applicant applied the weighting factor from Step 4 to the total unadjusted MRI scans in Step 3 to estimate the total number of adjusted MRI scans that would be needed

in its total service area and in each of the primary, secondary and tertiary service areas. See the tables that illustrate the calculations on page 141 of the application.

Step 6: Calculate the number of fixed MRI scanners needed in the proposed service area 2023-2028 – The applicant divided the estimated number of adjusted MRI procedures from Step 5 by 4,992, which is the Wake County MRI planning threshold as stated in the 2023 SMFP, and then subtracted the number of fixed MRI scanners located in the 23-ZIP code target service area. Based on those calculations the applicant determined that the target service area has low access to fixed MRI services. The applicant states there are currently nine fixed MRI scanners in the 23-ZIP code service area, two of which are located in Wake County. Those two scanners operated at 155% of the planning threshold, according to the 2023 SMFP.

Step 7: Determine Raleigh Radiology Knightdale unadjusted MRI scan history by ZIP code from CY 2020-2023 (annualized) – Relying on internal data, the applicant examined its unadjusted MRI utilization from CY 2020-2023 (annualized) and determined that approximately 60% of all MRI scans performed at Raleigh Radiology Knightdale during that time originated from the six ZIP codes that comprise the applicant's primary service area. The applicant states the remaining 17 ZIP codes provided nearly 25% of all Raleigh Radiology Knightdale's MRI scans during that same time. The applicant notes the utilization data is based on the leased mobile MRI scanner historically available 40 hours per week and 50 weeks per year. See the tables that illustrate the data on pages 143-144 of the application.

Step 8: Forecast Raleigh Radiology Knightdale unadjusted MRI scans by year at target area population CAGR for CY 2024-2027 – The applicant multiplied the previous year's unadjusted MRI scans from Step 7 by the 1.3%, .5% and 0.7% CAGRs in each of the primary, secondary and tertiary service areas, respectively, from Step 1. The applicant holds the unadjusted MRI scans constant at the 2023 number of scans for the remaining ZIP codes, counties and other states. The applicant notes it has historically referred many patients from the 23 ZIP code service area to its other Raleigh Radiology locations because the mobile MRI scanner at the Knightdale location is unable to accommodate all of its patients who need MRI services due to its limited availability. See the tables that illustrate the calculations on page 146 of the application.

Step 9: Add back unadjusted MRI scans from the service area that are referred to the other Raleigh Radiology locations – The applicant states a fixed MRI scanner would allow it to serve more patients it historically referred to its other locations. The applicant assumes some of those patients would still prefer other Raleigh Radiology locations and projects to recapture 85% of those previously referred patients from its primary service area, 15% from its secondary service area and 10% from its tertiary service area. The applicant assumes it would recapture 1% of its patients from the remaining ZIP codes, other North Carolina counties and other states. See the tables that illustrate the calculations on pages 148-149 of the application.

Step 10: Estimate total unadjusted scans by year at Raleigh Radiology Knightdale for CYs 2024-2027 – The applicant estimates total unadjusted MRI scans to be performed at Raleigh Radiology Knightdale in each of the interim and first three project years, CYs 2024-

2027 by adding the number of scans per year from Step 8 to the recaptured scans from Step 9. The applicant assumes no downtime between the date the existing mobile MRI service terminates at the Knightdale location and the fixed MRI service becomes operational. The applicant projects the fixed MRI will be operational October, 2024, and projects to capture 25% of both projected growth and recaptured MRI scans in the three month interim period of October 2024-December 2024. See the tables that illustrate the calculations on pages 150-151 of the application.

Step 11: Determine adjusted MRI procedures at all Raleigh Radiology, LLC locations from CYs 2020-2023 – The applicant analyzed historical utilization at all of its locations and calculated a four-year average percentage distribution of base and complex MRI scans, as defined in the 2023 SMFP, performed at its existing diagnostic centers. The applicant assumes that four-year average will remain constant through all three project years. See the table that illustrates these calculations on page 151 of the application.

Step 12: Forecast adjusted MRI procedures at Raleigh Radiology Knightdale for CYs 2024-2027 – The applicant projected the adjusted MRI procedures to be performed at Raleigh Radiology Knightdale by multiplying the total unadjusted scans from Step 10 by the four-year average percentage distribution of scan types from Step 11, then multiplying each product by the weighting factor from the 2023 SMFP. See the table that illustrates those calculations on page 152 of the application.

Step 13: Evaluate the impact of the recaptured scans on other Raleigh Radiology, LLC locations – The applicant states on page 152 that “*RRLLC MRI scans have been increasing at an average annual rate of 4.27 percent since 2019.*” However, the project analyst examined the exhibits that contain supporting calculations, as well as the tables in Section C that contain supporting calculations. The tables in the Exhibits and in Section C reflect an average annual growth rate of 11.95% across Raleigh Radiology, LLC locations from CY 2019-2023. Therefore, the project analyst concludes that statement on page 152 is a typographical error and the remainder of the analysis reflects an understanding of a growth rate of 11.95% as evidenced by the Exhibits and the calculations in Section C.

The applicant assumes the historical growth rate would continue through the three project years, CYs 2024-2027. The applicant assumes that MRI utilization at its locations other than Raleigh Radiology Knightdale would increase at a rate consistent with the projected population growth in each patient residence county. The applicant states it will continue the mobile MRI service at other Raleigh Radiology LLC locations once the proposed fixed MRI scanner is operational. See the tables that illustrate those calculations on pages 152-153 of the application.

Step 14: Determine historical Raleigh Radiology, LLC average MRI scan per patient – The applicant examined its internal data from CY 2020-2023 to calculate average MRI scans per patient, since one patient may receive more than one scan per visit. The applicant determined the four-year average MRI scans per patient from CY 2020-2023 was 1.25. See the table that illustrates the data and calculations on page 154 of the application.

Step 15: Calculate the distribution of MRI patients by Raleigh Radiology Knightdale geographic subgroup from CY 2024-2027 – The applicant divided the total number of unadjusted scans by ZIP code per year from Step 10 by the average scans per patient from Step 14 to project the number and percentage of patients to be served in each of the ZIP codes that comprise its service area. The applicant assumes the patients projected for the interim partial year of January – September 2024 do not include those patients who have historically been referred to other Raleigh Radiology, LLC locations and who are projected to return to Raleigh Radiology Knightdale. See the tables that illustrate the calculations on pages 155-156 of the application.

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

- There is a need determination in the 2023 SMFP for a fixed MRI scanner in the Wake County MRI service area and this proposed project will meet that need.
- The applicant’s projections of MRI scans to be performed are supported by its historical mobile MRI volumes, historical average MRI scans per patient and population growth projections.
- The applicant adequately demonstrates that its proposed fixed MRI scanner is reasonably expected to perform more than 3,494 adjusted MRI procedures in the third full fiscal year of operation following the completion of the proposed project, which exceeds the requirement 10A NCAC 14C .2703(a)(7)(a).

Access to Medically Underserved Groups

In Section C, page 68, the applicant states:

“... Raleigh Radiology facilities accept all patients regardless of gender, gender preference, race, ethnicity, age, income, religion, or disability status. Raleigh Radiology has a generous charity care policy, see Exhibit L.4.”

The applicant provides additional information regarding service to medically underserved groups on pages 68-71.

On page 71, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

Raleigh Radiology Knightdale Estimated Percentages

PAYOR GROUP	ESTIMATED PERCENTAGE OF PATIENTS IN 3RD FULL FY
Low Income Persons	8.5%
Racial and Ethnic Minorities	49.5%
Women	61.5%
Persons with Disabilities	10.4%
Persons 65 and Older	41.0%
Medicare Beneficiaries	26.9%
Medicaid Beneficiaries	4.4%

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 has historically provided access to its mobile MRI services to underserved groups.
- The applicant states that all patients will continue to receive equitable access to MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located in a diagnostic center under development in Garner. Upon project completion, the applicant will own and operate a total of five fixed MRI scanners, one of which will be located at Duke Imaging Garner.

Patient Origin

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1”*. In Chapter 5, page 31, the 2023 SMFP defines the service area for Acute Care Beds as *“...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.”* In Figure 5.1 on page 36 of the 2023 SMFP Wake County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner in a previously approved diagnostic center under development in Garner in Wake County. 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.

In Section C, page 29, the applicant states the proposed diagnostic center is under development and thus has no historical patient origin.

In Section C page 30, the applicant provides projected patient origin for the first three project years, FYs 2026-2028, for the proposed fixed MRI services, as summarized below:

Duke Imaging Garner Projected Patient Origin by ZIP Code and County

ZIP CODE/COUNTY	1 ST FULL FY 07/01/2025-06/30/2026		2 ND FULL FY 07/01/2026-06/30/2027		3 RD FULL FY 07/01/2027-06/30/2028	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
27529/Wake	277	14.2%	423	14.2%	573	14.2%
27520/Johnston	243	12.4%	371	12.4%	503	12.4%
27527/Johnston	194	9.9%	296	9.9%	401	9.9%
27610/Wake	372	19.0%	567	19.0%	768	19.0%
27545/Wake	167	8.5%	255	8.5%	345	8.5%
27591/Wake	129	6.6%	196	6.6%	266	6.6%
27603/Wake	282	14.4%	429	14.4%	582	14.4%
Other*	294	15.0%	448	15.0%	607	15.0%
Total	1,957	100.0%	2,984	100.0%	4,044	100.0%

*The applicant states on page 30 that "Other" includes "less than 1% of patients from the remaining North Carolina counties and other states".

In Section C, page 31 the applicant provides an additional table to illustrate projected patient origin by county, as shown below:

Duke Imaging Garner Projected Patient Origin by County

COUNTY	1 ST FULL FY 07/01/2025-06/30/2026		2 ND FULL FY 07/01/2026-06/30/2027		3 RD FULL FY 07/01/2027-06/30/2028	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Wake	1,226	62.6%	1,869	62.6%	2,533	62.6%
Johnston	438	22.4%	667	22.4%	904	22.4%
Other*	294	15.0%	448	15.0%	607	15.0%
Total	1,957	100.0%	2,984	100.0%	4,044	100.0%

*The applicant states on page 31 that "Other" includes "less than 1% of patients from the remaining North Carolina counties and other states".

In Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the applicant's proposed service area for diagnostic imaging services approved in Project ID #J-12073-21 and its mobile MRI service at the Garner location.

Analysis of Need

In Section C, pages 32-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need identified in the 2023 SMFP for a fixed MRI scanner in Wake County.

- Statewide MRI utilization increased by a CAGR of 1.8% from 2017-2022, and the number of statewide MRI procedures performed during the same time increased by a CAGR of 2.7%, according to data obtained from the NCOSBM, 2019-2023 SMFPs and the proposed 2024 SMFP. The applicant states Wake County MRI utilization increased by a CAGR of 5.0%, and the number of MRI procedures performed in Wake County increased by a CAGR of 7.1% from 2017-2021 (see pages 34-35).
- Historical DUHS outpatient MRI utilization demonstrates a need for additional MRI capacity in Wake County. The applicant analyzed its historical Wake County MRI utilization from FY 2019-2023 (annualized) and determined its inpatient MRI utilization increased by a CAGR of 1.0%, its outpatient MRI utilization by 8.1% and overall MRI utilization increased by a CAGR of 7.3% during that time. The applicant states historical MRI utilization underscores the need for the proposed fixed MRI scanner (see pages 35-36).
- The applicant proposes to develop the proposed fixed MRI scanner at a previously approved imaging center, thereby creating a diagnostic center which the applicant states will provide quality MRI services and interpretation by DUHS radiologists, which will enhance patient access to lower cost non-hospital based MRI services (see page 36).
- The applicant is developing a 60,000 square foot medical office building at the proposed site in Garner, which will provide primary care, urgent care, pediatric care, specialty care, physical and occupational therapy and laboratory services. It is this location for which the applicant was approved in Project ID #-J-12328-23 to develop a diagnostic center with mammography and ultrasound. The same location will house the proposed fixed MRI scanner, thereby creating a new geographic point of access for fixed MRI and other imaging services in a growing area of Wake County. The applicant states DUHS has a broad MRI referral base throughout the Triangle area and Wake County. Through that referral base, DUHS provides specialized MRI scan interpretation, which encourages physicians and primary care providers to refer patients to the DUHS network (see pages 36-37).
- Service area population growth indicates the need for additional fixed MRI capacity. The applicant analyzed population growth projections from the NCOSBM and found that the Wake County population is projected to increase by a CAGR of 2.0% between 2023-2028. According to the applicant, the proposed fixed MRI catchment area population is projected to increase by a 7.8% CAGR during that same time. In particular, the data shows that the over 65 cohort, which is the population group that accounted for approximately 40% of DUHS's outpatient imaging services in FY 2022, is projected to increase by a CAGR of 5.1% from 2023-2028. With the projected population growth from 2023-2028 in Wake County as a whole and in the catchment area that comprises the proposed service area, the applicant states the proposed fixed MRI scanner is needed to meet current and future patient demand (see pages 37-39).

Projected Utilization for proposed fixed MRI scanner

In Section Q, Form C.2b, the applicant provides projected utilization for the first three project years, FYs 2026-2028 (07/1-06/30), as illustrated in the following table:

Duke Imaging Garner Projected Utilization-Fixed MRI			
	1ST FULL FY FY 2026	2ND FULL FY FY 2027	3RD FULL FY FY 2028
Number of Units	1	1	1
# Procedures (unweighted)	1,957	2,984	4,044
# Weighted Procedures	2,135	3,254	4,411

In Section Q, Form C.2b, the applicant also provides projected utilization for the entire diagnostic center, as illustrated in the following table:

Duke Imaging Garner Projected Utilization			
	1ST FULL FY FY 2026	2ND FULL FY FY 2027	3RD FULL FY FY 2028
Mammography			
Number of Units	1	1	1
# Procedures	709	975	975
Ultrasound			
Number of Units	1	1	1
# Procedures	1,637	2,240	2,240

The mammography and ultrasound equipment projected utilization was provided for information only, since that equipment is not a part of this application. On Form C.2b, page 101, the applicant also provides a table to illustrate projected utilization for its approved mobile MRI scanner (Project ID #J-12378-23), for information purposes. The utilization analysis that follows pertains only to the proposed fixed MRI scanner that is the subject of this application.

In Section Q, “*Form C.2a and C.2b Utilization – Assumptions and Methodology*”, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI, as summarized below:

Step 1: Identify Garner fixed MRI scanner catchment area – The applicant identified seven ZIP codes that are within a 15-20 minute drive time of the proposed imaging center. The applicant states that, based on drive times, it anticipates that MRI volume will primarily originate from the identified ZIP codes. The applicant examined historical MRI utilization from the identified catchment area at its other facilities in Wake County. See the tables and maps that illustrate the applicant’s analysis on pages 102-104 of the application.

Step 2: Project DUHS outpatient MRI procedures from the catchment area – The applicant projects overall MRI utilization of all DUHS facilities that provide fixed or mobile MRI services from the identified catchment area will increase at a rate of 2% annually from 2023-2028, consistent with the projected Wake County population growth. See the table that illustrates projected utilization at all DUHS Wake County facilities on page 104 of the application.

Step 3: Project shift of volume from other DUHS facilities to the Garner facility – The applicant projects that a percentage of patients currently served at other DUHS facilities for MRI services will shift their care to the proposed Garner location for the following reasons as listed on page 104:

- *“Convenient geographic location, the first for Duke imaging services in this part of Wake County*
- *Colocation with primary and specialty physician services in the same medical office building complex*
- *Preference of payors and patients for IDTF over hospital-based services*
- *Backlog/capacity constraints at DUHS existing sites as volumes at highly utilized sites continue to increase”*

The applicant projects a ramp up from 30% to 50% over the three project years as the proposed diagnostic center becomes known by DUHS patients. The applicant states it projects only one-half of the ramp-up volume will actually shift their care from existing DUHS imaging facilities to the proposed Garner facility. See the tables that illustrate these calculations on page 105 of the application.

Step 4: Project incremental share of catchment area volume – The applicant projects to serve other residents of the proposed catchment area in addition to those patients who are projected to shift their care from other Wake County DUHS imaging facilities. Based on increased geographic access and patient convenience for fixed MRI services and the lower cost to patients of an outpatient imaging facility, the applicant projects to incrementally capture 2.0% of the catchment area population who need fixed MRI services in project year one, 3.5% in project year two, and 5.0% in project year three. See the tables that illustrate these calculations on pages 105-106 of the application.

Step 5: Project unadjusted MRI procedures from the catchment area – The applicant combines the number of MRI procedures to be performed in each of the first three project years based on the shift of existing DUHS patients from other Wake County imaging facilities and the incremental share of patients projected to be captured as described in Steps 3 and 4. See the table that illustrates these calculations on page 107 of the application.

Step 6: Project immigration from outside the catchment area – Based on DUHS historical patient origin for its Wake County facilities with MRI services, the applicant projects that 15% of its total patients to be served by the proposed fixed MRI services at Duke Imaging Garner will originate from counties outside of Wake County in each of the three project years. See the table that illustrates these calculations in on page 108 of the application.

Step 7: Project adjusted MRI procedures – Based on historical DUHS percentage of outpatient MRI procedures performed with and without contrast for FY 2022, the applicant projects the number of adjusted MRI procedures to be performed in each of the three project years. See the tables that illustrate these calculations on page 108 of the application.

The applicant also projected the number of MRI scans to be performed at each of the other Wake County DUHS locations using similar methodologies, as summarized below:

Projected MRI utilization at Duke Imaging North Raleigh – In Project ID #J-12073-21, the applicant was approved to develop a fixed MRI scanner in a diagnostic center, Duke Imaging North Raleigh (DUNR). That application is currently under appeal, but the applicant includes projected utilization for that fixed MRI, assuming it will be developed as approved.

The applicant states its outpatient MRI utilization on its existing scanners has continued to increase after the Agency's review of Project ID #J-12073-21; therefore, the applicant assumes the utilization projections approved in that application are still reasonable. The applicant adjusted the project start date as a result of the appeal. The applicant provides a table to illustrate those projections on page 109 of the application.

Projected MRI Utilization at Duke Raleigh Hospital – The applicant analyzed historical utilization on the existing fixed MRI scanners at Duke Raleigh Hospital from FY 2019-2023 (annualized at the time of the application). The applicant notes the development of Duke Imaging Holly Springs in June of 2020 redirected some MRI volume to that southwest Wake County location and the development of MRI services at Duke Imaging Heritage in northern Wake County has also redirected MRI volume to that location. The applicant states that, despite the volume shift, utilization at Duke Raleigh Hospital has continued to increase. The applicant projects MRI services at Duke Raleigh Hospital will increase at the same rate as the Wake County projected population growth of 2.0%, which is reasonable given the historical CAGR for outpatient MRI services was 8.1% from FY 2019-2023. The applicant projects additional volume shift to Duke Imaging Garner when that project is developed, and assumes the historical percentage of inpatient and outpatient MRI procedures involving contrast will remain constant through the first three project years. The applicant provides tables to illustrate historical and projected utilization at Duke Raleigh Hospital on pages 108-112.

Projected Utilization at Duke Imaging Holly Springs – The applicant was approved for a fixed MRI scanner at its Holly Springs location, which began operating in June 2020. The applicant examined historical utilization from the beginning of operation through FY 2023, annualized. The applicant shows historical utilization during that time increased by 37.3% from, FY 2020-2022, and then annualized growth from FY 2022-2023 at 13.8%. The applicant projects future MRI utilization at the Holly Springs location to increase by a CAGR of 4.5%, which the applicant states is reasonable, given historical utilization at the Holly Springs location and DUHS total MRI utilization across all of its facilities which provide MRI services. The applicant accounted for a shift of patients who would seek MRI services at the Garner diagnostic center, and assumes the historical percentage of inpatient and outpatient MRI procedures involving contrast will remain constant through the first three project years. The applicant provides tables to illustrate historical and projected utilization at Duke Imaging Holly Springs on pages 113-114.

Projected Mobile MRI utilization – The applicant notes this application represents a change of scope for the previously approved Project ID #J-12378-23 and states the mobile MRI projections approved in that application have not changed as a result of this proposal. The

applicant provides tables that illustrate the previously approved mobile MRI projections on page 115.

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

- There is a need determination in the 2023 SMFP for a fixed MRI scanner in the Wake County fixed MRI scanner service area and this proposed project will meet that need.
- The applicant’s projections of MRI scans to be performed are supported by DUHS historical MRI volumes on its existing fixed MRI scanners, projected population growth and projected shift from its other MRI services’ sites.
- The applicant adequately demonstrates that its existing and proposed fixed MRI scanners are reasonably expected to perform more than 3,494 adjusted MRI procedures in the third full fiscal year of operation following the project completion, as required by 10A NCAC 14C .2703(a)(7)(a).
- The applicant adequately demonstrates that its existing mobile MRI scanner is reasonably expected to perform more than 3,160 adjusted MRI procedures in the third full fiscal year of operation following project completion, as required by 10A NCAC 14C .2703(a)(8)(a).

Access to Medically Underserved Groups

In Section C, page 44, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to DUHS’s MRI services, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, disability, or sexual orientation.”

The applicant provides additional information on pages 44-45 of the application. On page 45, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons*	10.4%
Racial and ethnic minorities	33.0%
Women	51.0%
Persons with disabilities**	--
Persons 65 and older	32.8%
Medicare beneficiaries	32.8%
Medicaid beneficiaries	8.7%

*The applicant states on page 45 that this category reflects “percentage of Medicaid and charity care patients.”

** The applicant states on page 45 that DUHS does not maintain data regarding the number of disabled persons it serves.

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 has historically provided access to MRI services to underserved groups and states it will continue to do so.
- The applicant states patients will receive appropriate medical services regardless of ability to pay and states it has policies in place to ensure access to all services, including MRI services.
- The applicant states that all patients will continue to receive equitable access to low-cost MRI services with the approval of the proposed fixed MRI.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, where the applicant currently provides MRI services on two MRI scanners. One unit is a legacy MRI scanner (a “grandfathered” fixed MRI scanner owned by Alliance and leased to Wake Radiology), and the other is a mobile MRI scanner owned by Wake Radiology that provides services to supplement the legacy unit. Upon project completion, the applicant will terminate the contract for the legacy MRI but continue to provide mobile MRI services; thus, the applicant will operate one fixed MRI scanner along with mobile services at its Cary location.

Patient Origin

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1”. In Chapter 5, page 31, the 2023 SMFP defines the service area for Acute Care Beds as “...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.” In Figure 5.1 on page 36 of the 2023 SMFP Wake

County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner at an existing diagnostic center in Cary in Wake County. 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.

In Section C, pages 34-35, the applicant provides historical patient origin for its existing MRI services at Wake Radiology Cary for the last full FY, CY 2022, as summarized below:

**Wake Radiology Cary Historical Patient Origin
 Fixed MRI Services, CY 2022**

COUNTY	# PATIENTS	% OF TOTAL
Wake	3,661	86.2%
Harnett	138	3.3%
Lee	82	1.9%
Durham	56	1.3%
Other*	309	7.3%
Total	4,246	100.0%

*On page 34 the applicant provides a list of North Carolina counties it includes in "other". The applicant states "other" also includes other states.

**Wake Radiology Cary Historical Patient Origin
 Total Facility, CY 2022**

COUNTY	# PATIENTS	% OF TOTAL
Wake	26,076	86.9%
Harnett	638	2.1%
Johnston	533	1.8%
Lee	475	1.6%
Other*	2,286	7.6%
Total	30,008	100.0%

*On page 35 the applicant provides a list of North Carolina counties it includes in "other". The applicant states "other" also includes other states.

In Section C pages 36-37, the applicant provides projected patient origin for the first three project years, CYs 2025-2027, for the proposed fixed MRI services and for all diagnostic imaging services at Wake Radiology Cary, as summarized below:

Wake Radiology Cary Projected Patient Origin - MRI Services

COUNTY	1 ST FULL FY CY 2025		2 ND FULL FY CY 2026		3 RD FULL FY CY 2027	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Wake	3,892	86.2%	4,090	86.2%	4,298	86.2%
Harnett	147	3.3%	154	3.3%	162	3.3%
Lee	87	1.9%	92	1.9%	96	1.9%
Durham	60	1.3%	63	1.3%	66	1.3%
Other*	328	7.3%	345	7.3%	363	7.3%
Total	4,514	100.0%	4,743	100.0%	4,985	100.0%

*On page 36 the applicant provides a list of North Carolina counties it includes in "other". The applicant states "other" also includes other states.

Wake Radiology Cary Projected Patient Origin – Total Facility

COUNTY	1 ST FULL FY CY 2025		2 ND FULL FY CY 2026		3 RD FULL FY CY 2027	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Wake	27,236	86.9%	27,734	86.9%	28,252	86.9%
Harnett	666	2.1%	679	2.1%	691	2.1%
Johnston	557	1.8%	567	1.8%	577	1.8%
Lee	496	1.6%	505	1.6%	515	1.6%
Other*	2,388	7.6%	2,431	7.6%	2,477	7.6%
Total	31,343	100.0%	31,917	100.0%	32,512	100.0%

*On page 37 the applicant provides a list of North Carolina counties it includes in "other". The applicant states "other" also includes other states.

In Section C, page 36, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical patient origin data for fixed MRI services at Wake Radiology Cary.

Analysis of Need

In Section C, pages 38-52, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need in the 2023 SMFP for an additional fixed MRI scanner in Wake County.
- Need for additional freestanding fixed MRI capacity in Wake County based on utilization trends. The applicant examined utilization data for hospital based and freestanding fixed MRIs in Wake County and determined that utilization of freestanding MRI scanners increased nearly 20 times faster than that of hospital based fixed MRI scanners, in part because of the cost savings to patients (pages 38-41).
- Need for additional fixed MRI capacity within the Wake Radiology system. The applicant compared utilization among Wake County’s freestanding fixed MRI

providers and determined that Wake Radiology performed the highest number of total adjusted MRI scans in FFY 2021. The applicant states the partnership established between UNC Rex Health Care and Wake Radiology contributed to the utilization increase even during the anomalous COVID-19 pandemic, as many patients seeking MRI services at the hospital were referred to Wake Radiology's freestanding facilities. The applicant states the location of Wake Radiology facilities throughout Wake County also contributed to the increase in utilization, because many patients were able to access a Wake Radiology facility. Additionally, the applicant states many of Wake Radiology radiologists are specialists who can offer patients specialized scans to more effectively serve patients. The applicant also states that increased demand for fixed MRI services in Wake County is driven by residents of surrounding counties who continue to seek MRI and other health care services in Wake County (pages 41-46).

- Need for additional fixed MRI capacity specifically at Wake Radiology Cary. The applicant states Wake Radiology Cary currently provides MRI services via a vendor contract, which is supplemented by a mobile unit as well. Despite both units serving patients, the utilization at Wake Radiology Cary, particularly since the partnership with UNC Rex Health Care, increased by a CAGR of 10.2% from CY 2019-2021. Since the existing fixed unit is contracted, the applicant is not able to upgrade to advanced technology and proposes in this application to acquire a 3T MRI scanner (the existing contracted unit is a 1.5T scanner). The applicant also examined population data for Cary and surrounding towns. The data shows that Cary is the fastest growing Wake County municipality, behind Raleigh. The proposed Cary location will effectively and efficiently serve current and future patients (pages 46-49).
- Data provided by the applicant from the NCOSBM shows the population in Wake County from 2013-2023 is projected to increase by a CAGR of 2.0%, surpassing Mecklenburg County projected growth. The applicant cites additional data that shows Wake County is among the fastest growing counties in the country. Additionally, the 65 and over population cohort in Wake County is projected to increase by 22.3% by 2027, according to data provided by the applicant from NCOSBM. The applicant states the older population groups are those most likely to seek medical care and imaging services, particularly MRI services. Thus, the applicant states that it will be able to provide fixed MRI services in a freestanding setting that will efficiently and cost-effectively serve Wake County and surrounding counties' residents.

Projected Utilization

In Section Q, Form C.2b, the applicant provides projected utilization for the interim and first three project years, CYs 2025-2027 for the proposed fixed MRI scanners and other imaging services currently in place at Wake Radiology Cary, as illustrated in the following table:

Wake Radiology Cary Projected Utilization

	INTERIM YEAR CY 2024	1 ST FULL FY CY 2025	2 ND FULL FY CY 2026	3 RD FULL FY CY 2027
CT Scanner				
# Units	1	1	1	1
# Scans	4,732	4,744	4,757	4,770
# HECT Units	7,792	7,813	7,835	7,856
Fixed X-ray (incl. fluoro)				
# Units	2	2	2	2
# Procedures	7,061	6,947	6,834	6,724
Mammography				
# Units	4	4	4	4
# Procedures	17,258	17,769	18,110	18,552
MRI Scanner				
# Units	1	1	1	1
# Procedures (unweighted)	5,044	5,301	5,571	5,855
# Weighted Procedures	5,476	5,755	6,048	6,356
Nuclear Medicine				
# Units	1	1	1	1
# Procedures	943	959	974	990
Ultrasound				
# Units	7	7	7	7
# Procedures	10,034	10,295	10,564	10,839
DEXA				
# Units	1	1	1	1
# Procedures	2,545	2,580	2,616	2,652

In Section Q, “Form C Utilization – Assumptions and Methodology”, the applicant provides the assumptions and methodology used to project utilization for the proposed fixed MRI, as summarized below:

- The applicant states its fiscal year is a calendar year. The applicant projects that the proposed fixed MRI scanner will be operational on September 1, 2024. The applicant states its first three full FYs are CYs 2025-2027. The applicant states it uses the terms “scan” and “procedure” interchangeably throughout the application, and historical data is provided in calendar years, consistent with the applicant’s FY.
- The applicant examined total Wake Radiology MRI utilization from CY 2019-22 and calculated a CAGR for each type of scan provided at each of the Wake Radiology locations, on both fixed and mobile scanners. The applicant states overall, total adjusted scans increased by a CAGR of 5.4% during that time. The applicant notes that MRI volume at UNC Health Rex Hospital declined, and attributes that shift to the partnership entered into between Wake Radiology and UNC Health Rex Hospital and patients shifting their MRI services to outpatient facilities. The applicant projects growth of fixed MRI scanners at all Wake Radiology locations using one half of the historical CAGR. The applicant projects no growth in MRI services for the MRI

scanner at UNC Health Rex Hospital. The applicant projects utilization of its mobile MRI scanners by applying the projected population growth of 2.0% through all three project years. See the tables that illustrate the applicant's projections on pages 113-115 of its *Assumptions* in Section Q.

- The applicant states it has two locations in Cary, on opposite sides of the town. The applicant projects that some of the volume will shift from the Wake Radiology Cary location to the other Cary facility, Wake Radiology Panther Creek. The applicant provides tables to illustrate these calculations on page 116 of its *Assumptions* in Section Q.
- The applicant states UNC Health Rex Hospital owns a fixed MRI scanner that was previously approved to be relocated to the UNC Health Rex Holly Springs Hospital after at least one year of operation of the hospital. The applicant anticipates that scanner will become operational at the Holly Springs hospital in CY 2025. The applicant notes that historical adjusted MRI volume at the main campus of UNC Health Rex already exceeded the minimum performance standards promulgated in 10A NCAC 14C .2700 [in CY 2022, MRI volume on two scanners was 11,208, which is 5,604 scans per MRI scanner]. The applicant states that, even with the addition of the proposed fixed MRI scanner, the total MRI volume at all Wake Radiology locations in Wake County will exceed the minimum performance standard. The applicant provides tables to illustrate these calculations on pages 116-118 of its *Assumptions* in Section Q.
- The applicant projected future MRI utilization on the two mobile MRI scanners by applying the 2.0% projected population growth rate for Wake County per NCOSBM. The applicant states it believes these growth rates to be reasonable, given the historical utilization and the projected growth and aging of the Wake County population detailed by the applicant in Section C.4. The applicant provides a table to illustrate projected mobile MRI utilization by itself on page 118 of its *Assumptions* in Section Q.

The applicant provides projected utilization for the other medical diagnostic equipment operated by Wake Radiology for information purposes; however, none of that equipment is reviewable in this application.

The following table, from page 119 of Section Q, illustrates existing diagnostic equipment and historical utilization at Wake Radiology Cary:

Historical Utilization of Diagnostic Equipment at Wake Radiology Cary, CY 2019-2022

EQUIPMENT	CY 2019	CY 2020	CY 2021	CY 2022	CAGR
X-Ray	8,054	6,836	7,449	7,296	-3.2%
Mammogram	14,254	12,450	15,416	16,445	4.9%
Ultrasound	8,184	8,166	9,717	9,531	5.2%
CT (HECT Units)	7,626	8,112	6,580	7,750	0.5%
Nuclear Medicine	829	764	800	913	3.3%
DEXA	2,281	2,146	2,705	2,476	2.8%

On page 119 the applicant states it calculated HECT units “based on the historical ratio of HECT units to CT scans, which it projected to remain unchanged through the third project year.”

The applicant states that utilization of most of the other medical diagnostic equipment at Wake Radiology Cary increased from CY 2019 to CY 2022, despite a decline in CY20 as a result of the pandemic. The applicant states most diagnostic utilization has rebounded since that time. The applicant assumes that utilization of the other medical diagnostic equipment at Wake Radiology Cary will grow at one-half the historical rate. The applicant provides a table to illustrate projected utilization of the other diagnostic equipment on page 119 of its *Assumptions* in Section Q.

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

- There is a need determination in the 2023 SMFP for a fixed MRI scanner in the Wake County fixed MRI scanner service area, and this proposed project will meet that need.
- The applicant’s projections of MRI scans to be performed are supported by historical MRI volumes and growth on its existing fixed MRI scanners.
- The applicant provides letters of support that indicate projected referrals to Wake Radiology Cary for MRI services.
- The applicant adequately demonstrates that its existing and proposed fixed MRI scanners are reasonably expected to perform more than 3,494 adjusted MRI procedures in the third year of operation following the completion of the proposed project, as required by 10A NCAC 14C .2703(a)(7)(a).
- The applicant adequately demonstrates that its existing mobile MRI scanner is reasonably expected to perform more than 3,160 adjusted MRI procedures in the third full fiscal year of operation following project completion, as required by 10A NCAC 14C .2703(a)(8)(a).

Access to Medically Underserved Groups

In Section C, page 60, the applicant states:

“Wake Radiology ensures access to care for all patients regardless of income status, ability to pay, racial/ethnic origin, gender, age, physical or mental conditions, or any other characteristic that would classify a person as underserved or medically indigent. Wake Radiology will continue to ensure that services are rendered in compliance with:

1. Title VI of Civil Rights Act of 1963,
2. Section 504 of Rehabilitation Act of 1973, and
3. The Age Discrimination Act of 1975.”

On page 60, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

GROUP	ESTIMATED PERCENTAGE OF TOTAL PATIENTS DURING THE THIRD FULL FISCAL YEAR
Low income persons*	--
Racial and ethnic minorities	4.1%
Women	81.7%
Persons with disabilities*	--
Persons 65 and older	36.7%
Medicare beneficiaries	35.0%
Medicaid beneficiaries	2.0%

*The applicant states on page 61 that it does not maintain data that includes “the number of low income persons or handicapped persons it serves.”

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 has historically provided access to MRI services to underserved groups and states it will continue to do so.
- The applicant states estimated percentages are based on FY 2022 historical experience of patients served at Wake Radiology Cary.
- The applicant states it has a financial assistance policy that is available to all patients in need of assistance.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Remarks made at the public hearing
- Comments
- Response to comments

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
All Applications

None of the applicants proposes 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.

CA
All Applications

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

In Section E, pages 81-84, 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 fail to address the growing need for MRI services and improved access to reasonably priced MRI services in the service area. Additionally, the applicant states maintaining the status quo would ignore the need identified in the 2023 SMFP.
- Propose a different location – The applicant states it considered developing the proposed MRI scanner in a different Wake County location but determined the proposed Knightdale location has the highest need and is ideally located near major transportation arteries in the county. The applicant also states the data it provides shows the proposed location is among the least healthy population in the county and has limited access to MRI services. Thus, locating the proposed MRI scanner elsewhere is not an effective alternative.
- Replace a leased MRI scanner at another Raleigh Radiology location – The applicant considered replacing a fixed mobile MRI scanner that it leases at its Blue Ridge location but determined that to be a less effective alternative. If it were to replace the leased unit with a fixed MRI scanner, the mobile MRI scanner could then be reconverted to a mobile unit and potentially move outside of Wake County, thus putting additional strain on the remaining fixed MRI scanners in the county that are already

operating above capacity. Thus, replacing the legacy leased mobile MRI scanner at the Blue Ridge location is not an effective alternative.

- Acquire different equipment – The applicant considered acquiring a 3T MRI scanner but determined the cost of the scanner, the additional heat produced by the 3T scanner and the sound produced by the larger bore scanner do not outweigh the proven benefits of the proposed 1.5T fixed MRI scanner.
- Limit the proposed MRI scanner to a single specialty – The applicant evaluated the population density of Wake County against the available fixed MRI scanners providing general scans and the available fixed MRI scanners located at specialty practices and determined that there is a greater need for a fixed MRI scanner that provides a general range of MRI scans.

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

- The applicant states the 1.5T fixed MRI scanner proposed for the Raleigh Radiology Knightdale location in its application is the most effective way to meet the needs of its existing and proposed patients.
- The applicant states the alternatives were vetted by Raleigh Radiology medical staff and leadership.
- 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

In Section E, pages 56-57, 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:

- Increase MRI capacity at existing DUHS locations– The applicant considered locating the proposed fixed MRI scanner at one of its other Wake County locations, but determined that, given the distance from the proposed Garner location to other Wake County DUHS locations is between 17 and 24 miles, which is 30 minutes or more driving time. The applicant states the proposed location will more effectively serve its patients, increase patient convenience and coordination of care, and would expand geographic access to fixed MRI services in Wake County. Thus, the applicant states this is not an effective alternative.
- Select an alternative new location – The applicant considered an alternative Wake County location but determined the proposed location in Garner is a location with relatively few existing imaging services, and a location at which imaging services as well as primary and specialty services are already being developed. Thus, the applicant states an alternative location is not an effective alternative to meet patient needs.
- Contract for mobile MRI services – The applicant considered contracting for mobile MRI services at the Garner location, but that alternative would ignore the need determination for an additional fixed MRI scanner in Wake County. Additionally, mobile MRI services would not be as available as a fixed MRI scanner. Thus, the applicant states contracting for mobile MRI services is not an effective alternative to meet patient demand.

On page 56, the applicant states the proposed location is currently being developed as a medical office building with other health care, imaging and ambulatory services; thus it is the most effective location to meet DUHS patient needs.

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

- The applicant states that the proposal will provide fixed MRI services to a location where there are few imaging services available to patients.
- The applicant is already developing primary and specialty services, as well as imaging and ambulatory surgical services at the Garner location and adding fixed MRI capacity is a reasonable addition to the program under development.
- 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

In Section E, page 73, the applicant describes one alternative it considered and explains why that alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternative considered was:

- Develop the proposed fixed MRI scanner at a different location – The applicant states that by developing the proposed fixed MRI scanner at the Cary location in place of the existing legacy unit, it will secure long-term accessibility to fixed MRI services for its patients, improve quality of care, enhance the level of service (the legacy scanner is a 1.5T and the applicant proposes a 3.0T in this application), and reduce expenses associated with developing a fixed MRI scanner. Additionally, the Cary location is within a 15-minute drive time from many populous areas in Wake County. Thus, the applicant states developing the proposed fixed MRI scanner at an alternate location is not a reasonable alternative to meet patient needs.

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

- 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Comments
- Response to comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is 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.

C
All Applications

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

Capital and Working Capital Costs

In Section Q Form F.1a Capital Cost, page 118, the applicant projects the total capital cost of the project as shown in the table below:

Site Costs	\$5,000
Renovation Costs*	\$465,000
Medical Equipment	\$2,069,875
Miscellaneous Costs	\$414,241
Total	\$2,949,115

*Includes site costs, architect and engineering fees and furnishings.

In Section Q, page 158, 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:

- Renovation cost is based on an estimate from a general contractor which is provided in Exhibit F.1.
- Medical equipment cost is based on vendor quotations in Exhibit F.1.

In Section F, pages 87-88, the applicant states there will be no start-up costs or working capital associated with the project because Raleigh Radiology already provides MRI services at the Knightdale location and the proposed project will be an ongoing operation.

Availability of Funds

In Section F.2, page 85, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	RALEIGH RADIOLOGY, LLC
Loans	\$2,949,115
Total Financing	\$2,949,115

In Exhibit F-2, the applicant provides a letter dated June 13, 2023 signed by the Senior Vice President of First Citizens Bank confirming the bank’s willingness to consider a loan in the amount of \$3.5 million to provide funding for the proposed capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years (FY), of operation, calendar years (CY) 2025-2027, following project completion for MRI services and for the entire Raleigh Radiology Knightdale imaging services. In Form F.2b, the applicant projects that revenues will exceed operating expenses for MRI services in all three full fiscal years following project completion, as shown in the table below:

Raleigh Radiology Knightdale

	1 ST PY CY 2025	2 ND PY CY 2026	3 RD PY CY 2027
Total Procedures (unweighted)	5,695	5,730	5,766
Total Gross Revenues (Charges)	\$11,005,270	\$11,073,831	\$11,143,294
Total Net Revenue	\$1,972,337	\$1,984,624	\$1,997,073
Average Net Revenue per Procedure	\$346	\$346	\$346
Total Operating Expenses (Costs)	\$1,663,704	\$1,755,438	\$1,755,364
Average Operating Expense per Procedure	\$292	\$306	\$304
Net Income	\$308,633	\$229,186	\$241,709

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 166-167. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient services gross revenue is based on the applicant’s historical MRI payor mix at its Knightdale location which is projected to remain constant through the three project years.

- Charity care revenue is projected at 0.70% of gross revenue annually based on the applicant's CY 2022 historical experience operating diagnostic centers in Wake County.
- Bad debt is represented as 1.55% of gross revenue annually based on the applicant's CY 2022 historical experience operating diagnostic centers in Wake County.
- 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
- Response to written comments
- Remarks made at the public hearing

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.

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner. This proposal is filed as a cost over-run and change of scope for Project ID #J-12328-23 (develop a diagnostic center with mammography and ultrasound) since this proposal is to develop a fixed MRI scanner at the previously-approved diagnostic center in Garner.

Capital and Working Capital Cost

The certificate of need for Project ID #J-12328-23 approved a capital cost of \$2,422,000. The applicant states that the acquisition of the fixed MRI proposed in this application, combined with the additional construction, will require an additional \$5,270,000, for a total combined capital cost of \$7,692,000 ($\$2,422,000 + \$5,270,000 = \$7,692,000$).

The following table compares the capital cost approved in Project ID #J-12328-23, and the new projected capital cost, as reported on Form F.1b in Section Q of the application:

CAPITAL COST	PREVIOUSLY APPROVED CAPITAL COST J-12328-23	CAPITAL COST FOR THIS PROJECT J-12395-23	DIFFERENCE
Construction/Renovation	\$1,255,000	\$3,475,000	\$2,220,000
Architect/Engineering Fees	\$145,000	\$395,000	\$250,000
Medical Equipment	\$550,000	\$3,050,000	\$2,500,000
Non-Medical Equipment	\$110,000	\$360,000	\$250,000
Furniture	\$60,000	\$110,000	\$50,000
Other	\$302,000	\$302,000	\$0
Total	\$2,422,000	\$7,692,000	\$5,270,000

In Section Q, page 116 and referenced exhibits 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:

- The new costs associated with this project are the incremental costs of adding fixed MRI services to the previously-approved diagnostic center.
- Medical equipment cost is based on recent equipment quotes for comparable DUHS MRI projects. The applicant provides equipment quotes in Exhibit F.1b.
- Construction costs for the addition of the fixed MRI suite are based on a quote from a licensed architect.
- Other projected costs such as other equipment, IT and furniture, are based on the applicant’s experience with other MRI projects.

In Section F, page 65, the applicant projects the following difference in working capital costs:

WORKING CAPITAL COST	PREVIOUSLY APPROVED COST	NEW COST	DIFFERENCE
	J-12328-23	J-12395-23	CAPITAL COST FOR THIS PROJECT
Start-up Costs	\$37,949	\$70,039	\$32,090
Initial Operating Costs	\$1,438,609	\$1,438,609	\$0
Total	\$1,476,558	\$1,508,648	\$32,090

In Section F, page 65 the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The increase in start-up costs is related to additional staff, utility, medical supply and other associated costs for the addition of the proposed fixed MRI scanner.

- The applicant estimates the additional start-up costs specifically associated with developing the proposed fixed MRI scanner.

Availability of Funds

In Section F.2, page 64, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing	
TYPE	DUHS
Cash and Cash Equivalents, Accumulated Reserves, or OE*	\$5,270,000
Total Financing	\$5,270,000

*Owner’s Equity

In Section F, page 66 the applicant states the additional start-up costs associated with the development of the fixed MRI scanner will be funded with accumulated reserves of DUHS.

In Exhibit F.2(a), the applicant provides a letter dated June 9, 2023 signed by Interim Chief Financial Officer, Vice President, Corporate Controller and Chief Accounting Officer for DUHS that confirms the availability of up to \$7 million in current cash reserves to cover the increase in capital and start-up costs associated with this project. The letter also commits the necessary funds to the project development. Exhibit F.2(b) contains the audited financial statements for DUHS that documents the availability of sufficient funds for the increase in capital and working capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the last two full fiscal years following project completion, as shown in the table below:

Duke Imaging Garner MRI Services			
	1ST FFY	2ND FFY	3RD FFY
	07/01/25-06/30/26	07/01/26-06/30/27	07/01/27-06/30/28
Total Procedures (unweighted)	1,957	2,984	4,044
Total Gross Revenues (Charges)	\$2,169,152	\$3,373,491	\$4,663,123
Total Net Revenue	\$948,645	\$1,499,254	\$2,106,085
Average Net Revenue per Procedure	\$485	\$502	\$521
Total Operating Expenses (Costs)	\$1,013,361	\$1,134,654	\$1,198,310
Average Operating Expense per Procedure	\$518	\$680	\$296
Net Income	\$(64,716)	\$364,601	\$907,776

Numbers may not sum due to rounding

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, “*Form F.2 and F.3 Assumptions*” preceding Form F.2b. The applicant

adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Gross charges were calculated by DUHS ambulatory finance and reviewed by Duke Reimbursement and Revenue Management Team for appropriateness.
- Net reimbursement is based on the applicant's experience with its outpatient MRI population.
- 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
- Comments
- Response to written comments
- Remarks made at the public hearing

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 and working 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.

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

Capital and Working Capital Costs

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

Wake Radiology Cary Capital Cost

Construction Costs	\$407,000
Medical Equipment	\$2,600,813
Miscellaneous Costs	\$92,097
Total	\$3,099,909

Numbers may not sum due to rounding

In Section Q, “*Form F.1a Assumptions*”, 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:

- Construction costs are based on an estimate from a licensed architect with experience with similar projects.
- Medical equipment cost is based on vendor quotations.
- Furniture costs, non-medical equipment costs and consultant fees are based on the applicant’s experience with other diagnostic imaging projects.

In Section F.3, page 76, the applicant states there are no initial operating expenses or start-up costs associated with this project, since MRI services are currently provided at the Cary location.

Availability of Funds

In Section F, page 74 the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing

TYPE	WAKE RADIOLOGY IMAGING, LLC
Loans	\$3,099,909
Total Financing	\$3,099,909

In an unmarked exhibit, the applicant provides a June 14, 2023 letter signed by the Senior Vice President of First Citizens Bank confirming the bank’s willingness to consider a loan in the amount of \$3.1 million to provide funding for the proposed capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the interim year and the first three full FYs of operation, CYs 2025-2027, following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses in all three full fiscal years following project completion, as shown in the table below:

Wake Radiology Cary - Fixed MRI Services

	INTERIM YEAR 1/1/24- 12/31/24	1 ST PY CY 2025	2 ND PY CY 2026	3 RD PY CY 2027
Total Procedures (unweighted)*	5,044	5,301	5,571	5,855
Total Gross Revenues (Charges)	\$11,965,117	\$12,951,427	\$14,019,040	\$15,174,659
Total Net Revenue	\$4,357,284	\$4,716,464	\$5,105,252	\$5,526,088
Average Net Revenue per Procedure	\$864	\$890	\$916	\$944
Total Operating Expenses (Costs)	\$3,761,307	\$3,813,213	\$4,088,906	\$4,279,438
Average Operating Expense per Procedure	\$746	\$719	\$734	\$731
Net Income	\$595,977	\$903,251	\$1,016,346	\$1,246,650

From Form C.2b, Section Q

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, “*Form F.2 Assumptions*”. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Patient services gross revenue is based on the applicant’s historical CY 2022 payor mix and charge per procedure through all three project years, increased by 3% annually.
- Bad debt is based on the applicant’s CY 2022 historical experience.
- Contractual adjustments by payor and charity care are based on the projected difference between gross revenue and net revenue, based on the applicant’s CY 2022 historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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 and working 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.

- (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
 All Applications

The 2023 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” Therefore, for the purpose of this review, the fixed MRI scanner 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 currently located in the Wake County service area, summarized from Table 17E-1, pages 350-352 of the 2023 SMFP:

Wake County Fixed MRI Scanners

PROVIDER/OWNER	# OF FIXED SCANNERS	SERVICE TYPE	TOTAL MRI SCANS	ADJUSTED TOTAL
Duke Raleigh Hospital	2	Hospital Fixed	10,360	13,139
Rex Hospital Main	2	Hospital Fixed	7,554	11,373
Rex Hospital-UNC Rex Health Care of Cary	1	Hospital Fixed	0	0
WakeMed	2	Hospital Fixed	10,771	15,465
WakeMed Cary Hospital	1	Hospital Fixed	4,235	5,625
Cardinal Points Imaging of the Carolinas Midtown / Pinnacle Health Services of North Carolina, LLC	1	Freestanding Fixed	5,435	5,912
Duke Health Arrington Radiology / DUHS	1	Freestanding Fixed	0	0
Duke Imaging Holly Springs / DUHS	1	Freestanding Fixed	1,763	1,938
Duke Imaging North Raleigh / DUHS	0	Freestanding Fixed	0	0
Raleigh Neurology Associates, P.A.	1	Freestanding Fixed	4,829	5,298
Raleigh Neurology Imaging, PLLC / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	5,109	5,586
Raleigh Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	6,715	7,146
Raleigh Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	6,658	7,106
The Bone and Joint Surgery Clinic	1	Freestanding Fixed	2,208	2,208
Wake Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	3,794	4,136
Wake Radiology Diagnostic Imaging/ Alliance Healthcare Services, Inc.	1	Freestanding Fixed	4,667	5,072
Wake Radiology MRI / WR Imaging, LLC	1	Freestanding Fixed	3,478	3,867
Wake Radiology MRI / WR Imaging, LLC	1	Freestanding Fixed	4,342	4,889

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

In Section G, page 93, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Wake County fixed MRI service area. The applicant states:

“The proposed project will offset some of the MRI access disparity in Wake County. Even though MRI is now a routine diagnostic tool, MRI scanner access is not uniform among North Carolina counties.”

On pages 94-96, the applicant states the service area has limited fixed and mobile MRI capacity, increasing need and the proposed service area is currently underserved. 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 fixed MRI scanner in the Wake County fixed MRI scanner service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments and responses to those comments
- Remarks made at the public hearing
- 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.

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

In Section G, page 68, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Wake County fixed MRI service area. On page 68 the applicant states:

“The projected as proposed will not result in any unnecessary duplication of existing or approved facilities with fixed MRI scanners in Wake County. This project is designed to increase geographic access and address capacity constraints at existing Duke fixed MRI locations. DUHS MRI utilization has increased significantly across the system in recent years, reflecting a growing demand for these services. Rather than expanding its capacity to meet this growing need at an existing site, DUHS is developing incremental fixed MRI services in an underserved area. There is only one fixed MRI scanner located in Garner, which is operated by Wake Radiology. During FY2022, Wake Radiology’s Garner-based fixed MRI scanner utilization exceeded the 3,494 adjusted MRI performance standard. Given the location of the existing scanners in Wake County, the Garner area is therefore the region within the service area most in need of additional MRI access.”

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 fixed MRI scanner in the Wake County fixed MRI scanner service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing
- 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.

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

In Section G, page 83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in the Wake County fixed MRI scanner service area. The applicant states:

“The proposed project involves the development of a fixed MRI scanner at Wake Radiology Cary, which is in response to a need determination in the 2023 SMFP for an additional fixed MRI scanner to be located in Wake County. As discussed in Section C.4, demand for freestanding MRI services in Wake County is growing quickly, especially the high-quality, sub-specialized MRI services offered at Wake Radiology facilities. Wake Radiology Cary in particular needs permanent fixed MRI capacity to support the increasing demand for its outpatient MRI services in the large and growing Cary and Apex communities. By developing the proposed scanner at its Cary facility in place of the existing contracted MRI service at that location, Wake Radiology will secure long term accessibility to MRI services for its patients, improve the quality of care, enhance the level of care provided with the proposed 3T scanner, and reduce the expenses associated with offering fixed MRI services.”

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 fixed MRI scanner in the Wake County fixed MRI service area.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanners in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing
- 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.

- (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

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI service for the partial interim and first three full fiscal years (FY), calendar years (CY) 2025-2027 as summarized below:

Raleigh Radiology Knightdale Proposed Staffing				
POSITION	PARTIAL YEAR (10/1/24- 12/31/24)	1ST FULL FY CY 2025	2ND FULL FY CY 2026	3RD FULL FY CY 2027
Radiology Technologist	1.40	5.68	5.74	5.81
Clerical	0.50	2.06	2.06	2.06
Total	2.00	8.00	8.00	8.00

Numbers may not sum due to rounding.

The assumptions and methodology used to project staffing are provided in Section Q, page 180. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 99, the applicant states it currently has staff in place, but will hire three new MRI Radiology Technologists; however, not all will be FTEs. In Section H, page 99, the applicant describes the methods used to recruit or fill new positions. The applicant provides examples of its proposed training and continuing education programs on pages 99-100 and referenced exhibits.

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 demonstrates it currently provides fixed mobile MRI services and has staff in place to accommodate the proposed fixed MRI services.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on its historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed fixed MRI services at Duke Imaging Garner for the first three full fiscal years, as summarized below:

Duke Imaging Garner Staffing

POSITION	1 ST FULL FY FY 2026	2 ND FULL FY FY 2027	3 RD FULL FY FY 2028
Radiology Technologist- MRI	2.24	2.24	2.24
Financial Care Counselor	1.11	1.11	1.11
Total	3.35	3.35	3.35

The assumptions and methodology used to project staffing are provided in Section Q, “*Form H Assumptions*”. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 70, the applicant states additional MRI staff are needed to accommodate the proposed fixed MRI scanner.

The application for Project ID #J-12328-23 adequately demonstrated the availability of resources, including health manpower and management personnel to provide the proposed services to provide the proposed services. In this application, the applicant adequately demonstrates the availability of additional staffing resources for the proposed fixed MRI scanner because the applicant adequately demonstrates its intent to provide additional staff for the proposed fixed MRI services as needed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

In Section Q Form H Staffing, the applicant provides the projected FTE positions for the entire facility, which includes the proposed fixed MRI service for the first three full FYs, CYs 2025-2027 as summarized below:

POSITION	1ST FULL FY CY 2025	2ND FULL FY CY 2026	3RD FULL FY CY 2027
MRI Technologists	5.0	5.0	5.0
MRI Patient Services Rep	2.2	2.2	2.2
Diagnostic Technician	4.1	4.1	4.1
CT Technologist	2.1	2.1	2.1
Nuclear Medicine	1.0	1.0	1.0
Ultrasound Technologist	6.0	6.0	6.0
Mammography Tech	8.0	8.0	8.0
Total	28.4	28.4	28.4

The assumptions and methodology used to project staffing are provided in Section Q, “*Form H Assumptions*”. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 85-86, 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 provides fixed MRI services at the Cary location and has experience in hiring and training staff for the provision of those services.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff will acquire and maintain appropriate certification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

Ancillary and Support Services

In Section I, page 101, the applicant identifies the necessary ancillary and support services for the proposed services. On page 102, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently contracts for mobile MRI services at Raleigh Radiology Knightdale and currently provides the necessary ancillary and support services.
- The applicant states it will continue to provide the necessary ancillary and support services following the addition of the proposed fixed MRI scanner and provides a letter in Exhibit I.1 from Raleigh Radiology, LLC attesting to the ongoing availability of these services.

Coordination

In Section I, page 103, the applicant states it maintains a vast network of relationships with local health care and social services providers in the service area. The applicant provides letters of support and letters confirming provision of ancillary and support services in Exhibits I.1a-I.1d. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently has established relationships with other local healthcare and social services providers.
- The applicant confirms it will continue those relationships upon project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

Ancillary and Support Services

In Section I, page 72, the applicant states the necessary ancillary and support services for the proposed MRI services are the same as those approved in Project ID #J-12328-23 and explains that each of the ancillary and support services will still be made available following the addition of the proposed fixed MRI scanner. The applicant adequately demonstrates that the necessary ancillary and support services will be made available as approved in Project ID #J-12328-23.

Coordination

In Section I, page 72, the applicant states the addition of fixed MRI services to the facility approved in Project ID #J-12328-23 will be integrated into the DUHS system and affiliates and will not affect the integration of the approved facility into that system. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system as approved in Project ID #J-12328-23.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

Ancillary and Support Services

In Section I, pages 87-88, the applicant identifies the necessary ancillary and support services for the proposed MRI services and explains how each ancillary and support service will be made available. The applicant 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 provides a letter signed by the Managing Partner of Wake Radiology Imaging, LLC and Wake Diagnostic Imaging, Inc. that documents the availability of the necessary ancillary and support services.
- The applicant provides support letters from area physicians who express support for the project and indicate an intent to refer patients for MRI services.

Coordination

In Section I, page 88, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently has existing relationships with the local healthcare community and other healthcare and community benefit pharmacies.
- The applicant documents that it offers education, outreach and screening programs with community organizations and social services organizations and states it will continue those relationships following the addition of the proposed fixed MRI scanner.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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 projects 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 projects 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 is 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
All Applications

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

In Section K, page 106, the applicant states the project involves renovating 1,330 square feet of unused office space to accommodate the proposed fixed MRI and support space. Line drawings are provided in Exhibit K-2.

On 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 the project involves relatively inexpensive renovation to existing space in the existing diagnostic center with no service interruption for patients.
- The applicant provides a letter from a construction company in Exhibit K.2 verifying the construction plans.

On page 107, 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 project will reduce the cost of providing MRI services because it will no longer bear an obligation to a third party vendor for mobile MRI services and will provide increased accessibility to fixed MRI services for its patients.
- The applicant states it will operate the proposed fixed MRI services with no increase in revenue per scan.

On page 108, 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
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

In Section K, page 75 the applicant states the project involves constructing 1,102 square feet of new space in the previously approved diagnostic center (Project ID# J-12328-23). The applicant states the additional 1,102 square feet of new construction will accommodate the proposed MRI, control room and prep space. Line drawings are provided in Exhibits K.1(a) and K.1(b).

On page 77 the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the applicant's statement that the project architect and project manager reviewed the necessary construction plans and provided an estimate based on that review. The applicant provides a cost estimate from a licensed architect in Exhibit F.1(a).

On page 77 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 it has extensive experience in developing and operating imaging services and has carefully considered facility design and construction as well as equipment selection to ensure the design is necessary and appropriate to enhance health care access for its patients.
- The applicant states the project will not increase charges or projected reimbursement for the proposed services.

On pages 77-78, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

In Section K, page 91, the applicant states the project involves renovating 1,241 square feet of existing space in the existing diagnostic center to develop the proposed fixed MRI scanner in the same location as the existing contracted legacy fixed MRI scanner.

On pages 91-92, 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 proposes to renovate existing space in which an existing leased fixed MRI scanner is situated, thus requiring minimal renovation and cost.
- The applicant provides a detailed construction cost estimate in Exhibit C.1-1.

On page 92, 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 project will not increase costs and charges to the public because the costs incurred to develop the project are minimal since they involve renovating existing space rather than new construction.
- The applicant states the project will be developed to ensure efficient design and compliance with all applicable federal, state and local building codes, as well as requirements for energy efficiency and consumption.
- The applicant states the project will ultimately reduce the fixed expenses associated with offering the fixed MRI services at the proposed location because it will no longer contract for fixed MRI services through a third-party vendor. Thus, there will be no undue increases in costs or charges to the public.

On page 92, the applicant identifies any applicable energy saving and water conservation features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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
 Raleigh Radiology, LLC
 Wake Radiology Diagnostic Imaging, Inc.

NA
 Duke University Health System, Inc.

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

In Section L, page 110, the applicant provides the historical payor mix during CY 2022 for its existing diagnostic center services, as shown in the table below:

**Raleigh Radiology Knightdale
 Diagnostic Imaging Historical Payor Mix CY 2022**

PAYOR CATEGORY	DIAGNOSTIC IMAGING SERVICES AS PERCENT OF TOTAL
Self-Pay	4.1%
Charity Care*	--
Medicare**	26.9%
Medicaid**	4.4%
Insurance**	60.5%
Other^	4.1%
Total	100.0%

*On application page 110, the applicant states charity care is 0.7% of net patient revenue.

**Includes managed care plans

^On application page 110, the applicant states "other" includes Worker's Compensation, TriCare, VA and "other payors"

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

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	<i>Not available</i>	61.50%
Male	<i>Not available</i>	38.50%
Unknown	<i>Not available</i>	--
64 and Younger	56.0%	82.80%
65 and Older	44.0%	17.20%
American Indian	<i>Not available</i>	1.00%
Asian	<i>Not available</i>	2.90%
Black or African-American	<i>Not available</i>	26.40%
Native Hawaiian or Pacific Islander	<i>Not available</i>	0.05%
White or Caucasian	<i>Not available</i>	50.50%
Other Race	<i>Not available</i>	19.10%
Declined / Unavailable	<i>Not available</i>	--

On page 112 the applicant states Raleigh Radiology, LLC locations do not collect patient data regarding gender or race.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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.

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

This application is a cost overrun and change of scope for Project ID #J-12328-23. The diagnostic center will be a new facility and thus, has no patient origin to report.

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner

In Section L, page 95, the applicant provides historical payor mix for Wake Radiology Cary during CY 2022, as shown in the table below:

Wake Radiology Cary Historical Payor Mix CY 2022

PAYOR CATEGORY	PERCENT OF TOTAL PATIENTS SERVED
Self-Pay	1.2%
Charity Care*	--
Medicare**	35.0%
Medicaid**	2.0%
Insurance**	60.4%
Other (Includes Workers Compensation and TRICARE)	1.4%
Total	100.0%

*The applicant states its internal data *“does not include Charity Care as a payor source for patients.”*

**Includes managed care plans

In Section L, page 96, the applicant provides the following comparison:

	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	81.7%	51.1%
Male	18.3%	48.9%
Unknown	0.0%	0.0%
64 and Younger	63.3%	87.4%
65 and Older	36.7%	12.6%
American Indian	0.1%	0.8%
Asian	1.8%	8.3%
Black or African-American	2.3%	21.0%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	29.5%	67.1%
Other Race	0.3%	2.8%
Declined / Unavailable	66.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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
All Applications

J-12393-23 / Raleigh Radiology, LLC / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 114, the applicant states it is under no obligation under federal regulations to provide uncompensated care or community service or access by minorities and handicapped persons.

In Section L, page 114, the applicant states that no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina in the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

This application is a cost overrun and change of scope for Project ID #J-12328-23. The diagnostic center will be a new facility and thus, has no past performance.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 97, the applicant states that it has no obligation to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 98, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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
All Applications

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

In Section L, page 115, the applicant projects the following payor mix for the entire facility and for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

**Raleigh Radiology Knightdale
 Diagnostic Imaging Projected Payor Mix CY 2027**

PAYOR CATEGORY	DIAGNOSTIC IMAGING SERVICES AS PERCENT OF TOTAL
Self-Pay	4.1%
Charity Care*	--
Medicare**	26.9%
Medicaid**	4.4%
Insurance**	60.5%
Other^	4.1%
Total	100.0%

*On application page 115, the applicant states charity care is 0.7% of net patient revenue.

**Includes managed care plans

^On application page 110, the applicant states "other" includes Worker's Compensation, TRICARE, VA and "other payors"

**Raleigh Radiology Knightdale
 MRI Services Projected Payor Mix CY 2027**

PAYOR CATEGORY	DIAGNOSTIC IMAGING SERVICES AS PERCENT OF TOTAL
Self-Pay	1.7%
Charity Care*	--
Medicare**	28.1%
Medicaid**	4.9%
Insurance**	61.0%
Other^	4.3%
Total	100.0%

*On application page 115, the applicant states charity care is 0.7% of net patient revenue.

**Includes managed care plans

^On application page 110, the applicant states "other" includes Worker's Compensation, TRICARE, VA and "other payors"

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.7% of total fixed MRI services will be provided to self-pay patients, 28.1% to Medicare patients and 4.9% to Medicaid patients.

In Section Q, page 166, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on Raleigh Radiology Knightdale's historical payor mix during CY 2022.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

In Section L, page 84, the applicant projects the following payor mix for the proposed fixed MRI services and for the entire imaging facility during the third full fiscal year of operation following project completion, as shown in the table below:

**Duke Imaging Garner Projected Payor Mix
 MRI Services FY 2028**

PAYOR CATEGORY	MRI SERVICES AS PERCENT OF TOTAL
Self-Pay	0.3%
Charity Care	2.0%
Medicare*	35.7%
Medicaid*	10.9%
Insurance*	47.8%
Workers Compensation	0.4%
TRICARE	1.7%
Other	1.2%
Total	100.0%

*Includes managed care plans

**Duke Imaging Garner Projected Payor Mix
 Total Facility FY 2028**

PAYOR CATEGORY	PERCENT OF TOTAL PATIENTS SERVED
Self-Pay	0.3%
Charity Care	1.7%
Medicare*	32.8%
Medicaid*	8.7%
Insurance*	54.1%
Workers Compensation	0.2%
TRICARE	1.5%
Other	0.7%
Total	100.0%

*Includes managed care plans

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 0.3% of total facility and MRI services will be provided to self-pay patients, 1.7% and 2.0% of total facility and MRI services, respectively to charity care patients, 32.8% and 35.7% of total facility and MRI services, respectively to Medicare patients and 8.7% and 10.9% of total facility and MRI services, respectively to Medicaid patients.

On page 84 the applicant provides the assumptions and methodology used to project MRI payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on the applicant’s historical payor mix for outpatient MRI services specifically in the ZIP codes within its proposed service area.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner

In Section L, page 99, the applicant projects the following payor mix for the proposed MRI services during the third full fiscal year of operation following project completion, as shown in the table below:

Wake Radiology Cary Projected Payor Mix CY 2027

PAYOR CATEGORY	MRI SERVICES AS PERCENT OF TOTAL
Self-Pay	0.7%
Charity Care*	--
Medicare**	44.1%
Medicaid**	1.7%
Insurance**	51.9%
Other (Includes Workers Compensation and TRICARE)	1.6%
Total	100.0%

*The applicant states its internal data “does not include Charity Care as a payor source for patients.”

**Includes managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.7% of total fixed MRI services will be provided to self-pay patients, 44.1% to Medicare patients and 1.7% to Medicaid patients.

On page 98, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on FY 2022 historical payor mix for the applicant's existing facility's MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

In Section L, page 117, the applicant adequately describes the range of means by which patients will have access to the proposed fixed MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

In Project ID# J-12328-23, the Agency determined the applicant adequately demonstrated it would offer a range of means by which a person would have access to its services. The applicant proposes no changes in the current application which would affect that determination. In Exhibit C.4, the applicant provides physician letters of support that confirm referrals to Duke Imaging Garner for MRI services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner

In Section L, page 100, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments
- Remarks made at the public hearing

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
Raleigh Radiology, LLC
Duke University Health System, Inc.
CA
Wake Radiology Diagnostic Imaging, Inc.

Raleigh Radiology, LLC. In Section M, the applicant describes the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provides supporting documentation in the referenced exhibits.

Duke University Health System, Inc. In Project ID #J-12328-23, the Agency determined the applicant adequately demonstrated the extent to which health professional training programs in the area have or will have access to the facility for training purposes. The applicant proposes no changes in this application that would affect that determination.

Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC In Section M, page 101, the applicant describes the extent to which health professional training programs in the area have or will have access to its existing locations and its commitment to offer training programs at its additional locations. Prior to issuance of a certificate of need for its proposed project, should the applicant be approved, the applicant shall provide the Agency with documentation that an effort has been made to accommodate the clinical needs of health professional training programs at Wake Radiology Cary.

The Agency reviewed the:

- Applications
- Exhibits to the applications
- Written comments
- Responses to written comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that Raleigh Radiology, LLC's and Duke University Health System, Inc.'s applications adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore are conforming to this criterion. The application submitted by Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC is conforming to this criterion as conditioned.

(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.

All Applications

The 2023 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” 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 currently located in the Wake County service area, summarized from Table 17E-1, pages 350-352 of the 2023 SMFP:

Wake County Fixed MRI Scanners

PROVIDER/OWNER	# OF FIXED SCANNERS	SERVICE TYPE	TOTAL MRI SCANS	ADJUSTED TOTAL
Duke Raleigh Hospital	2	Hospital Fixed	10,360	13,139
Rex Hospital Main	2	Hospital Fixed	7,554	11,373
Rex Hospital-UNC Rex Health Care of Cary	1	Hospital Fixed	0	0
WakeMed	2	Hospital Fixed	10,771	15,465
WakeMed Cary Hospital	1	Hospital Fixed	4,235	5,625
Cardinal Points Imaging of the Carolinas Midtown / Pinnacle Health Services of North Carolina, LLC	1	Freestanding Fixed	5,435	5,912
Duke Health Arrington Radiology / DUHS	1	Freestanding Fixed	0	0
Duke Imaging Holly Springs / DUHS	1	Freestanding Fixed	1,763	1,938
Duke Imaging North Raleigh / DUHS	0	Freestanding Fixed	0	0
Raleigh Neurology Associates, P.A.	1	Freestanding Fixed	4,829	5,298
Raleigh Neurology Imaging, PLLC / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	5,109	5,586
Raleigh Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	6,715	7,146
Raleigh Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	6,658	7,106
The Bone and Joint Surgery Clinic	1	Freestanding Fixed	2,208	2,208
Wake Radiology / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	3,794	4,136
Wake Radiology Diagnostic Imaging/ Alliance Healthcare Services, Inc.	1	Freestanding Fixed	4,667	5,072
Wake Radiology MRI / WR Imaging, LLC	1	Freestanding Fixed	3,478	3,867
Wake Radiology MRI / WR Imaging, LLC	1	Freestanding Fixed	4,342	4,889

J-12393-23 / Raleigh Radiology, LLC /Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 119, the applicant states:

“RRKD will offer Wake County a new fixed MRI competitor. RRLLC nor any of its affiliate companies, owns or operates an MRI scanner. MRI services provided at RRKD are owned and operated by Akumin. As a new freestanding competitor in eastern Wake County, RRLLC will be able to ensure continued market competition. Ensuring this continued presence will sustain the competitive offering. For consumers and others for whom price is a concern will increase their awareness and request the same from other providers. This dynamic should work to contain prices at other clinics. It is also evident in the number of hospitals applying for freestanding MRI units that RRLLC has a competitive effect that will reduce costs for outpatients at local hospitals.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 120, the applicant states:

“The design of the facility supports a low-charge, low-reimbursement structure.

Raleigh Radiology Knightdale MRI will contain administrative costs by sharing overhead with RRLLC and with the rest of the Raleigh Radiology Knightdale diagnostic center. RRLLC will give it direct and immediate access to staff skilled in policies and procedures, billing, third-party contract negotiations, human resources, and facility management. Sharing in this talent pool will enable the center to function with a lean staff.”

See also Sections B, 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 states:

“The Applicant will pursue American College of Radiology accreditation for the proposed MRI scanner. This third party, peer reviewed oversight will provide transparency to the proposed project’s technical quality. The project will automatically participate in the Raleigh Radiology ACR Breast Center of Excellence program

All technical staff and physicians who read / interpret the studies will be required to maintain appropriate and current licensure and continuing education.”

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

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

“The facility will accept referred patients without regard to source of payment and has plans to provide charity for medical necessity. It will accept most third-party commercial payors, including the State Employees Medical plan, Tricare for military veterans, Medicaid and Medicare..

See also Sections B, 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 written comments
- Remarks made at the public hearing

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

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 88, the applicant states:

“By adding MRI services to the approved diagnostic center, this project will increase competition for those services in Wake County. This project creates a new service location in an area of the county with limited access to fixed MRI services, and expands DUHS MRI capacity in the county, increasing patient choice. DUHS currently operates a relatively small percentage of the existing fixed MRI scanners in the county. Therefore, the change in scope will increase competition for MRI services as well as for the other approved modalities.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 89, the applicant states:

“As with the other services to be offered at this location, the MRI services will be provided in an IDTF, which offers many patients and payors a lower-cost option than hospital-based services. See Section C for further discussion of the benefits of the proposed project in terms of geographic access and cost effectiveness.”

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

Regarding the impact of the proposal on quality, in Section N, page 89, the applicant states:

“The proposed facility will be part of the Duke University Health System, with a long-standing reputation for quality and safety and established oversight programs and policies and a robust financial assistance policy. Patients with a variety of potential clinical concerns can have their scans performed at this location, with the scans interpreted by Duke’s subspecialist radiologists, such as abdominal and musculoskeletal specialists.”

See also Sections B, 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 89, the applicant states:

“This project provides a new service location for MRI services in Wake County, increasing geographic access and patient choice. By developing a fixed MRI scanner in Garner, an area that is relatively underserved by MRI services, DUHS will specifically expand access to patients in that area with limited transportation and who may have easier access by public transportation to a closer facility.

The proposed facility will be part of the Duke University Health System, with a long-standing reputation for quality and safety and established oversight programs and policies and a robust financial assistance policy.”

See also Sections B, 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
- Response to written comments
- Remarks made at the public hearing

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

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 102, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to fixed MRI services... . By developing the proposed 3.0T scanner at Wake Radiology Cary in place of the existing contracted MRI service at that location, Wake Radiology will secure long term accessibility to MRI services for its patients, improve the quality of care, and reduce the expenses associated with offering fixed MRI services.”

Regarding the impact of the proposal on cost effectiveness, in Section B, pages 29-30, the applicant states:

“As a freestanding facility, Wake Radiology Cary provides MRI services at a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than they do freestanding services, meaning that the patient's out-of-pocket expenses are lower when receiving non-hospital-based care. ... the proposed project will increase access to low-cost, freestanding fixed MRI services in Wake County, and the partnership between Wake Radiology and UNC Health Rex will help to ensure patients receive MRI scans in the most appropriate setting, hospital-based or freestanding, based on each patient's unique situation.”

See also the remainder of Section B, and Sections C and F of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section B, page 28, the applicant states:

“Wake Radiology is committed to offering high quality care in an environment that is safe for patients, physicians, and staff. Wake Radiology promotes safety and manages risk by regularly assessing each practice facility for ways to better prevent and minimize any individual’s exposure to harm at that site. These measures will continue to guide Wake Radiology’s provision of services. The proposed project will allow Wake Radiology to expand its MRI capacity and reduce operating costs at Wake Radiology Cary – thus increasing overall quality and patient satisfaction while promoting competition for quality care in the region.”

See also the remainder of Section B, and Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section B, pages 27-28, the applicant states:

“Wake Radiology 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. Please see Exhibit B.20-2 for a copy of Wake Radiology’s Payment Plans for Patients Policy, which details Wake Radiology’s commitment to serve all patients regardless of age, race, sex, creed, religion, disability, or the patient’s ability to pay. ... Wake Radiology is not only easily accessible by these underserved groups, but by the remainder of the population as well. In addition to fair and equitable policies and procedures, Wake Radiology has undertaken many community-minded initiatives to make its services more accessible to all residents in the service area. In 2020, Wake Radiology provided over \$678,000 in charity care through Project Access, Alliance Medical Ministry, the Open Door Clinic, and contributions through its association with UNC Health Rex.”

See also the remainder of Section B, and 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
- Response to written comments
- Remarks made at the public hearing

Based on that review, the Agency concludes that the application is 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

J-12393-23 / Raleigh Radiology, LLC / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP.

In Section Q, Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of eight of this type of facility located in North Carolina.

In Section O, page 122, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care that occurred in either of its facilities. Diagnostic centers are not subject DHSR license requirements. After reviewing and considering information provided by the applicant, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at diagnostic center under development in Garner.

In Section Q, Form O, the applicant identifies the hospitals and other facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 17 of this type of facility located in North Carolina.

In Section O.4, page 91, the applicant states the facility is not an existing facility. The applicant also states that, during the 18 months immediately preceding the submittal of the application, it is not aware of any reported quality care issues at its existing diagnostic centers. Although diagnostic centers are not subject to DHSR license requirements, the applicant is part of Duke University Health (DUH). According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there was one incident at Duke University Hospital, for which the applicant was back in compliance on July 6, 2022. Additionally, there was one incident at Duke Raleigh Hospital, for which the applicant was back in compliance on May 24, 2023. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all DUH facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP

The applicant proposes to acquire one fixed MRI scanner to be developed at Wake Radiology Cary, for a total of one fixed MRI scanner. The applicant will continue to provide mobile MRI services at this location as well.

In Section Q, Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 15 of this type of facility located in North Carolina.

In Section O, page 105, the applicant states that, during the 18 months immediately preceding the submittal of the application, there was one incident related to quality of care that occurred at UNC Health Rex Hospital. The applicant states that the problem has been corrected. Diagnostic centers are not subject DHSR license requirements. After reviewing and considering information provided by the applicant, 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.

C-All Applications

The Criteria and Standards for Magnetic Resonance Imaging Scanners, promulgated in 10A NCAC 14C .2700, are applicable to this review.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

- (a) *An applicant proposing to acquire a **fixed MRI** scanner 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 fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*
- NA- **Raleigh Radiology.** As of the first day of the review period for this review, the applicant has no fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
- C- **DUHS.** In Section C, page 47 the applicant states it currently owns or operates three fixed MRI scanners in the fixed MRI scanner service area. However, according to the 2023 SMFP, the applicant owns or operates a total of four fixed MRI scanners in the Wake County fixed MRI scanner service area.
- C- **Wake Radiology.** In Section C, page 62 the applicant states it owns or operates five fixed MRI scanners in the fixed MRI scanner service area.
- (2) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*
- NA- **Raleigh Radiology.** As of the first day of the review period for this review, the applicant has no approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
- NA- **DUHS.** As of the first day of the review period for this review, the applicant has no approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.
- NA- **Wake Radiology.** In Section C, page 62 the applicant states that neither the applicant nor any related entity has been approved to own or operate a fixed MRI scanner located in the proposed fixed MRI scanner service area.
- (3) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed fixed MRI*

scanner service area during the 12 months before the application deadline for the review period;

-NA- **Raleigh Radiology.** In Section C, page 74 the applicant states that neither the applicant nor any related entity owns or operates a mobile MRI scanner in the proposed fixed MRI scanner service area.

-NA- **DUHS.** In Section C, page 47 the applicant states this question is not applicable.

-C- **Wake Radiology.** In Section C, pages 62-63 the applicant states Wake Radiology Imaging, a related entity, owns or operates two mobile MRI scanners in the proposed fixed MRI scanner service area.

(4) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;

-NA- **Raleigh Radiology.** In Section C, page 73 the applicant states that neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.

-NA- **DUHS.** In Section C, page 47 the applicant states this question is not applicable. Neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner in the proposed fixed MRI scanner service area.

-NA- **Wake Radiology.** In Section C, page 63 the applicant states that neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.

(5) provide projected utilization of the MRI scanners identified in Subparagraphs (a)(1) through (a)(4) of this Paragraph and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following completion of the project;

-C- **Raleigh Radiology.** In Section Q, Form C.2b and Section C, page 74, the applicant provides projected utilization for its proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.

-C- **DUHS.** In Section Q, Form C.2b, the applicant provides projected utilization for its existing fixed MRI scanners in Wake County and the proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.

-C- **Wake Radiology.** In Section Q, Form C.2b, the applicant provides projected utilization for its existing fixed MRI scanners and the proposed fixed MRI scanner, and the two existing mobile MRI scanners during each of the first three full fiscal years of operation following project completion.

- (6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (a)(5) of this Paragraph;*
- C- **Raleigh Radiology.** In Section Q, “*Raleigh Radiology Knightdale Need & Utilization Methodology*”, pages 134-156, the applicant provides projected utilization of the proposed fixed MRI scanner through the first three full fiscal years of operation following project completion.
- C- **DUHS.** In Section Q, “*Form C.2a and C.2b Utilization – Assumptions and Methodology*”, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed MRI scanners.
- C- **Wake Radiology.** In Section Q, “*Form C Assumptions and Methodology*”, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed MRI scanners and the two existing mobile MRI scanners.
- (7) *project that the fixed MRI scanners identified in Subparagraphs (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:*
- (a) *3494 or more adjusted MRI procedures per MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*
 - (b) *3058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*
 - (c) *1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and*

According to Table 17E-1, page 352 of the 2023 SMFP, there are currently 20 existing fixed MRI scanners in the Wake County fixed MRI scanner service area and one additional fixed MRI scanner for which a certificate of need was issued on October 15, 2023. Therefore, Subparagraph (a) applies to this review.

- C- **Raleigh Radiology.** In Section Q, Form C.2b, page 130, the applicant projects to provide more than 3,494 adjusted MRI procedures on the proposed fixed MRI scanner during the third full fiscal year of operation following project completion. In addition, in Exhibit C.5, page 12, the applicant projects to provide more than 3,494 adjusted MRI procedures on its fixed MRI scanner at its Cary location during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **DUHS.** In Section Q, Form C.2b, pages 97-100, the applicant projects to provide more than 3,494 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- C- **Wake Radiology.** In Section Q, Form C.2b, pages 110-119 the applicant projects to provide more than 3,494 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
 - (8) *Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of [operation following] completion of the proposed project.*
- NA- **Raleigh Radiology.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- NA- **DUHS.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- C- **Wake Radiology.** In Section Q, Form C.2b, the applicant projects that its existing mobile MRI scanners will perform at least 3,120 adjusted MRI procedures during the third full fiscal year of operation following project completion.
 - (b) *An applicant proposing to acquire a **mobile MRI** scanner 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 mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
 - (2) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
 - (3) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
 - (4) *identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
 - (5) *identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;*
 - (6) *provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;*
 - (7) *provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

- (8) *project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and*
- (9) *project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:*
 - (a) *3494 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;*
 - (b) *3058 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;*
 - (c) *1310 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;*

- NA- **Raleigh Radiology.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- NA- **DUHS.** The applicant does not propose in this application to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.
- NA- **Wake Radiology.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2023 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for the Wake County fixed MRI scanner service area in this review. Because all of the applications in this review collectively propose to develop three additional fixed MRI scanners to be located in the Wake County fixed MRI scanner service area, all of the applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of all of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review:

- **J-12393-23/ Raleigh Radiology, LLC /Acquire one fixed MRI scanner**
Raleigh Radiology, LLC proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at Raleigh Radiology Knightdale, an existing diagnostic center located in Knightdale.
- **J-12395-23 / Duke University Health System, Inc. / Acquire one fixed MRI scanner**
The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP to be located at a diagnostic center in Garner.
- **J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC / Acquire one fixed MRI scanner**
Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC propose to acquire one fixed MRI scanner pursuant to the need determination in the 2023 SMFP, to be located at Wake Radiology Cary.

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. All three applications are either conforming or conditionally conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, all three applications are equally effective alternatives.

Geographic Accessibility (Location within the Service Area)

As of the start date of this review and according to the 2023 SMFP, there are 20 existing fixed MRI scanners and one approved fixed MRI scanner located or to be located in Wake County. Fourteen of the existing and one approved fixed MRI scanners are located in the city of Raleigh. Three existing fixed MRI scanners are located in Cary. One existing fixed MRI scanner is located in Morrisville. One existing fixed MRI scanner is located in Garner. One existing fixed MRI scanner is located in Holly Springs. The application submitted by **Raleigh Radiology, LLC** proposes to locate its fixed MRI scanner in Knightdale. The application submitted by **Duke University Health System, Inc.** proposes to locate its fixed MRI scanner in Garner. The application submitted by **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** proposes to locate its fixed MRI scanner in Cary.

Therefore, for purposes of this comparative factor, the application submitted by **Raleigh Radiology, LLC** is a more effective alternative since it proposes to locate the fixed MRI scanner in a town that does not currently have a fixed MRI scanner. The applications submitted by **Duke University Health System, Inc.** and **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** are less effective alternatives because each proposes to locate a fixed MRI scanner in a town that currently has a fixed MRI scanner in place.

Competition (Patient Access to a New or Alternate Provider)

Generally, the introduction of a new or alternate provider in the service area would be a more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs for services in order to compete for patients. However, the expansion of an existing provider that currently owns or operates fewer services than another provider in the service area would also presumably encourage all providers in the service area to improve quality and/or lower costs in order to compete for patients.

Raleigh Radiology, LLC currently provides fixed MRI services on one leased installed MRI scanner in Wake County. Thus, as of the start date of this review, **Raleigh Radiology, LLC** did not own or operate any fixed MRI scanners in the Wake County fixed MRI scanner service area. **Duke University Health System, Inc.** currently operates two fixed MRI scanners at Duke Raleigh Hospital, one fixed MRI scanner at Duke Health Arrington Radiology and one fixed MRI scanner at Duke Imaging Holly Springs. Thus, as of the start date of this review, **Duke University Health System, Inc.** operates a total of four fixed MRI scanners in the Wake County fixed MRI scanner service area, which is 20% of the total fixed MRI scanners in the service area. **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC**, in partnership with UNC Health Rex Hospital, own or operate a total of five fixed MRI scanners in the Wake County fixed MRI scanner service area as follows: two fixed MRI scanners at Wake Radiology Raleigh, two hospital-based fixed MRI scanners in Raleigh and one fixed MRI scanner approved to be relocated to UNC Rex Holly Springs Hospital. Thus, as of the start date of this review, **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** and UNC Health Rex Hospital combined, owned or operated a total of five fixed MRI scanners in the Wake County fixed MRI scanner service area, which is 25% of the total fixed MRI scanners in the service area.

Therefore, with regard to patient access to a new or alternate fixed MRI provider in Wake County, the application submitted by **Raleigh Radiology, LLC** is the more effective alternative, because **Raleigh Radiology, LLC** does not control any of the fixed MRI services in the service area, and if approved for the fixed MRI scanner that is the subject of this review, would effectively provide patients with additional options for an alternate provider of fixed MRI services in the service area. The applications submitted by **Duke University Health System, Inc.** and **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** are less effective alternatives, because they currently control more of the fixed MRI inventory in the Wake County fixed MRI scanner service area.

Access by Underserved Groups

Underserved groups are 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, applications 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 Project Analyst compared each applicant’s projected Medicare revenue as a percentage of gross revenue. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.

MRI Services to Medicare Patients - Project Year 3

Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Raleigh Radiology LLC	\$3,131,266	\$11,143,294	28.1%
Duke University Health System, Inc.	\$1,631,549	\$4,663,123	35.0%
Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC	\$6,693,637	\$15,174,659	44.1%

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** projects that 44.1% of its MRI services will be provided to Medicare patients. The application submitted by **Duke University Health System, Inc.** projects that 35.0% of its fixed MRI services will be provided to Medicare patients. The application submitted by **Raleigh Radiology, LLC** projects that 28.1% of its fixed MRI services will be provided to Medicare patients. Therefore, with regard to service to Medicare patients, the application submitted by **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** is the more effective alternative.

Projected Medicaid

The Project Analyst compared each applicant’s projected Medicaid revenue as a percentage of gross revenue. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicaid patients in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

MRI Services to Medicaid Patients - Project Year 3

Applicant	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
Raleigh Radiology, LLC	\$546,021	\$11,143,294	4.9%
Duke University Health System, Inc.	\$503,839	\$4,663,123	10.8%
Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC	\$262,673	\$15,174,659	1.7%

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **Duke University Health System, Inc.** projects that 10.8% of its MRI services will be provided to Medicaid patients. The application submitted by **Raleigh Radiology, LLC** projects that 4.9% of its fixed MRI services will be provided to Medicaid patients. The application submitted by **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** projects that 1.7% of its fixed MRI services will be provided to Medicaid patients. Therefore, with regard to service to Medicaid patients, the application submitted by **Duke University Health System, Inc.** is the more effective alternative.

Projected Average Net Revenue per Weighted MRI Procedure

The following table compares the projected average net revenue per weighted MRI procedure for the third year of operation following project completion for each of the applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally regarding this comparative factor, the application proposing the lowest average net revenue per weighted MRI procedure is the more effective alternative.

Projected Average Net Revenue per Weighted MRI Procedure - Project Year 3

Applicant	Net Revenue	# of Weighted MRI Procedures	Average Net Revenue / Weighted MRI Procedure
Raleigh Radiology, LLC	\$1,997,073	6,130	\$326
Duke University Health System, Inc.	\$2,106,085	4,411	\$477
Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC	\$5,526,088	6,356	\$869

Source: Forms C.2b and F.2b for each application.

As shown in the table above, the application submitted by **Raleigh Radiology, LLC** projects the lowest average net revenue per weighted MRI procedure in the third operating year. The applications submitted by **Duke University Health System, Inc. and Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** project a higher average net revenue per weighted MRI procedure in the third operating year. However, **Duke University Health System, Inc.** does not include a line item for professional fees. **Raleigh Radiology, LLC** and **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** do include a line item for professional fees, which impacts net revenues. Therefore, this comparison is inconclusive.

Projected Average Operating Expense per Weighted MRI Procedure

The following table compares the projected average operating expense per weighted MRI procedure in the third year of operation for each of the applicants, based on the information provided in the

applicants’ pro forma financial statements (Section Q). Generally regarding this comparative factor, the application proposing the lowest average operating expense per weighted MRI procedure is the more effective alternative.

Projected Operating Expense per Weighted MRI Procedure - Project Year 3

Applicant	Operating Expense	# of Weighted MRI Procedures	Average Operating Expense / Weighted MRI Procedure
Raleigh Radiology, LLC*	\$1,321,405	6,130	\$215
Duke University Health System, Inc.	\$1,198,310	4,411	\$272
Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC*	\$2,583,833	6,356	\$399

Source: Forms C.2b and F.3b for each application.

*Professional fees were deducted from the operating expenses for Raleigh Radiology and Wake Radiology

As shown in the table above, the application submitted by **Raleigh Radiology, LLC** projects the lowest average operating expense per weighted MRI procedure in the third operating year. The applications submitted by **Duke University Health System, Inc. and Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** each project higher average operating expenses per weighted MRI procedure in the third operating year. Therefore, the application submitted by **Raleigh Radiology, LLC** is the most effective application with respect to projected average operating expense per weighted MRI procedure.

Summary

The following table lists the comparative factors and indicates whether each application was more effective or less effective for each 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	Raleigh Radiology, LLC	Duke University Health System, Inc.	Wake Radiology Imaging, Inc. and WR Imaging, LLC
Conformity with Review Criteria	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility	More Effective	Less Effective	Less Effective
Competition (Access to new or alternate provider)	More Effective	Less Effective	Less Effective
Access by Medicare Patients	Less Effective	Less Effective	More Effective
Access by Medicaid Patients	Less Effective	More Effective	Less Effective
Average Net Revenue per MRI Procedure	Inconclusive	Inconclusive	Inconclusive
Average Operating Expense per MRI Procedure	More Effective	Less Effective	Less Effective

All three applications as submitted are conforming to all applicable statutory and regulatory review criteria, and thus all applications are approvable standing alone. However, collectively they propose a total of three fixed MRI scanners in the Wake County fixed MRI scanner service area, but the need determination in the 2023 SMFP is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner in the service area can be approved.

As shown in the table above, the application submitted by **Raleigh Radiology, LLC** was determined to be a more effective alternative for the following three factors:

- Geographic Accessibility
- Competition (Access to a New or Alternate Provider)
- Projected Average Operating Expense per Weighted MRI procedure

As shown in the table above, the application submitted by **Duke University Health System, Inc.** was determined to be a more effective alternative for the following factor:

- Access by Medicaid patients

As shown in the table above, the application submitted by **Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** was determined to be a more effective alternative for the following factor:

- Access by Medicare patients

DECISION

Each application is individually conforming to the need determination in the 2023 SMFP for one fixed MRI scanner in the Wake County fixed MRI scanner service area, as well as individually conforming to all statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

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

- Project I.D. # **J-12393-23/ Raleigh Radiology, LLC** / Develop one fixed MRI scanner pursuant to the 2023 SMFP need determination

And the following applications are denied:

- Project I.D. # **J-12395-23 / Duke University Health System, Inc.** / Develop one fixed MRI scanner pursuant to the 2023 SMFP need determination
- Project I.D. # **J-12396-23 / Wake Radiology Diagnostic Imaging, Inc. and WR Imaging, LLC** / Develop one fixed MRI scanner pursuant to the 2023 SMFP need determination

Project I.D. # **J-12393-23/ Raleigh Radiology, LLC** is approved subject to the following conditions:

1. **Raleigh Radiology, LLC (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 to the need determination in the 2023 SMFP to be located in an existing diagnostic center located at 1101 Great Falls Court in Knightdale.**
3. **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 April 1, 2024.**
4. **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.**
5. **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.**