

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 6, 2024

Findings Date: September 6, 2024

Project Analyst: Cynthia Bradford

Co-Signer: Gloria C. Hale

Project ID #: J-12524-24

Facility: Duke Raleigh Hospital

FID #: 923421

County: Wake

Applicant: Duke University Health System, Inc.

Project: Acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion

### 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

Duke University Health System, Inc., herein after referred to as “DUHS” or “the applicant,” proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 State Medical Facilities Plan (SMFP) to be located in an outpatient clinic on the Duke Raleigh Hospital campus in Raleigh, Wake County, for a total of no more than three fixed MRI scanners upon project completion.

#### **Need Determination**

The 2024 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 2024 SMFP identified a need for one fixed MRI scanner in Wake County. The application was submitted in response to the need determination in the 2024

SMFP for one fixed MRI scanner in Wake County. Therefore, the application is consistent with the need determination in the 2024 SMFP.

### **Policies**

Two policies in Chapter 4 of the 2024 SMFP are applicable to this application: *Policy GEN-3: Basic Principles* and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

### **Policy GEN-3**

Policy GEN-3 on page 29 of the 2024 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.”*

In Section B, page 26, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states it is committed to maintaining the highest standards and quality of care, it will not discriminate on the basis of race, color, national origin, age, disability, gender, or sexual orientation, and will maximize healthcare value by developing the proposed fixed MRI scanner at a location that is highly utilized where there is a known and growing demand.

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 30 of the 2024 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 26-27, 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
- Written comments
- Remarks made at the public hearing
- Responses to comments

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.
- (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.

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The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

**Patient Origin**

The 2024 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.*” The applicant proposes to locate the fixed MRI scanner on the campus of Duke Raleigh Hospital 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.

Historical Patient Origin

In Section C, pages 28-31, the applicant provides the historical patient origin for its existing MRI services at DRAH for the last full fiscal year (July 1, 2022 - June 30, 2023), as shown below.

<b>Historical Fixed MRI Procedures Patient Origin Duke Raleigh Hospital</b>		
<b>County</b>	<b>Number of Patients</b>	<b>Percent of Total</b>
Alamance	28	0.4%
Alexander	1	0.0%
Ashe	2	0.0%
Beaufort	17	0.2%
Bertie	2	0.0%
Bladen	6	0.1%
Brunswick	40	0.5%
Buncombe	7	0.1%
Burke	2	0.0%
Cabarrus	3	0.0%
Caldwell	3	0.0%
Camden	1	0.0%
Carteret	33	0.4%
Caswell	3	0.0%
Catawba	5	0.1%
Chatham	23	0.3%
Cherokee	1	0.0%
Chowan	7	0.1%
Cleveland	2	0.0%
Columbus	12	0.2%
Craven	28	0.4%
Cumberland	124	1.7%
Currituck	5	0.1%
Dare	8	0.1%
Davie	1	0.0%
Duplin	14	0.2%
Durham	148	2.0%
Edgecombe	32	0.4%
Forsyth	1	0.0%
Franklin	324	4.4%
Gaston	5	0.1%
Gates	2	0.0%
Granville	63	0.9%
Greene	3	0.0%
Guilford	26	0.4%
Halifax	55	0.7%
Harnett	134	1.8%
Haywood	1	0.0%
Henderson	3	0.0%
Hertford	6	0.1%
Hoke	9	0.1%
Iredell	7	0.1%
Jackson	4	0.1%
Johnston	330	4.5%
Jones	3	0.0%
Lee	55	0.7%

Lenoir	14	0.2%
Madison	1	0.0%
Martin	11	0.1%
McDowell	1	0.0%
Mecklenburg	14	0.2%
Montgomery	3	0.0%
Moore	38	0.5%
Nash	134	1.8%
New Hanover	36	0.5%
Northampton	9	0.1%
Onslow	37	0.5%
Orange	46	0.6%
Pamlico	4	0.1%
Pasquotank	4	0.1%
Pender	18	0.2%
Perquimans	2	0.0%
Person	19	0.3%
Pitt	49	0.7%
Randolph	4	0.7%
Richmond	5	0.1%
Robeson	21	0.3%
Rockingham	6	0.1%
Rowan	2	0.0%
Sampson	34	0.5%
Scotland	9	0.1%
Stanly	1	0.0%
Surry	2	0.0%
Swain	3	0.0%
Transylvania	1	0.0%
Union	5	0.1%
Vance	76	1.0%
Wake	4,708	64.0%
Warren	14	0.2%
Washington	4	0.1%
Wayne	66	0.9%
Wilson	68	0.9%
Yancy	1	0.0%
Out of State	296	4.0%
Total # of Scans	7,355	100.0%

In Section C, pages 32-34, the applicant provides projected patient origin for the first three full fiscal years, FYs 2027-2029, for the proposed fixed MRI services, as summarized below:

Duke Raleigh Hospital  
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DRAH Fixed MRI Procedures	Duke Raleigh Hospital					
	1 <sup>st</sup> Full FY 07/01/2026 to 06/30/2027		2 <sup>nd</sup> Full FY 07/01/2027 to 06/30/2028		3 <sup>rd</sup> Full FY 07/01/2028 to 06/30/2029	
	County	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients
Alamance	68	0.5%	69	0.5%	70	0.5%
Alexander	2	0.0%	2	0.0%	2	0.0%
Alleghany	0	0.0%	0	0.0%	0	0.0%
Anson	2	0.0%	2	0.0%	2	0.0%
Ashe	0	0.0%	0	0.0%	0	0.0%
Avery	0	0.0%	0	0.0%	0	0.0%
Beaufort	37	0.3%	38	0.3%	38	0.3%
Bertie	2	0.0%	2	0.0%	2	0.0%
Bladen	12	0.1%	12	0.1%	12	0.1%
Brunswick	72	0.6%	73	0.6%	74	0.6%
Buncombe	14	0.1%	14	0.1%	14	0.1%
Burke	2	0.0%	2	0.0%	2	0.0%
Cabarrus	4	0.0%	4	0.0%	4	0.0%
Caldwell	0	0.0%	0	0.0%	0	0.0%
Camden	0	0.0%	0	0.0%	0	0.0%
Carteret	70	0.5%	71	0.5%	72	0.5%
Caswell	2	0.0%	2	0.0%	2	0.0%
Catawba	10	0.1%	10	0.1%	10	0.1%
Chatham	23	0.2%	24	0.2%	24	0.2%
Cherokee	2	0.0%	2	0.0%	2	0.0%
Chowan	10	0.1%	10	0.1%	10	0.1%
Clay	0	0.0%	0	0.0%	0	0.0%
Cleveland	2	0.0%	2	0.0%	2	0.0%
Columbus	14	0.1%	14	0.1%	14	0.1%
Craven	27	0.2%	28	0.2%	28	0.2%
Cumberland	258	2.0%	261	2.0%	263	2.0%
Currituck	6	0.0%	6	0.0%	6	0.0%
Dare	20	0.2%	20	0.2%	20	0.2%
Davidson	4	0.0%	4	0.0%	4	0.0%
Davie	4	0.0%	4	0.0%	4	0.0%
Duplin	31	0.2%	32	0.2%	32	0.2%
Durham	391	3.0%	395	3.0%	399	3.0%
Edgecombe	39	0.3%	39	0.3%	40	0.3%
Forsyth	18	0.1%	18	0.1%	18	0.1%
Franklin	469	3.7%	474	3.7%	479	3.7%
Gaston	6	0.0%	6	0.0%	6	0.0%
Gates	2	0.0%	2	0.0%	2	0.0%
Granville	96	0.7%	97	0.7%	98	0.7%
Greene	10	0.1%	10	0.1%	10	0.1%
Guilford	59	0.5%	59	0.5%	60	0.5%
Halifax	74	0.6%	75	0.6%	76	0.6%
Harnett	219	1.7%	221	1.7%	223	1.7%
Haywood	2	0.0%	2	0.0%	2	0.0%
Henderson	2	0.0%	2	0.0%	2	0.0%
Hertford	6	0.0%	6	0.0%	6	0.0%

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Hoke	20	0.2%	20	0.2%	20	0.2%
Hyde	4	0.0%	4	0.0%	4	0.0%
Iredell	6	0.0%	6	0.0%	6	0.0%
Jackson	4	0.0%	4	0.0%	4	0.0%
Johnston	535	4.2%	541	4.2%	547	4.2%
Jones	6	0.0%	6	0.0%	6	0.0%
Lee	106	0.8%	107	0.8%	108	0.8%
Lenoir	35	0.3%	36	0.3%	36	0.3%
Martin	16	0.1%	16	0.1%	16	0.1%
McDowell	0	0.0%	0	0.0%	0	0.0%
Mecklenburg	23	0.2%	24	0.2%	24	0.2%
Montgomery	4	0.0%	4	0.0%	4	0.0%
Moore	66	0.5%	67	0.5%	68	0.5%
Nash	205	1.6%	207	1.6%	209	1.6%
New Hanover	88	0.7%	89	0.7%	90	0.7%
Northampton	20	0.2%	20	0.2%	20	0.2%
Onslow	72	0.6%	73	0.6%	74	0.6%
Orange	111	0.9%	113	0.9%	114	0.9%
Pamlico	4	0.0%	4	0.0%	4	0.0%
Pasquotank	8	0.1%	8	0.1%	8	0.1%
Pender	35	0.3%	36	0.3%	36	0.3%
Perquimans	4	0.0%	4	0.0%	4	0.0%
Person	33	0.3%	34	0.3%	34	0.3%
Pitt	84	0.7%	85	0.7%	86	0.7%
Polk	2	0.0%	2	0.0%	2	0.0%
Randolph	20	0.2%	20	0.2%	20	0.2%
Richmond	12	0.1%	12	0.1%	12	0.1%
Robeson	55	0.4%	55	0.4%	56	0.4%
Rockingham	12	0.1%	12	0.1%	12	0.1%
Rowan	6	0.0%	6	0.0%	6	0.0%
Rutherford	2	0.0%	2	0.0%	2	0.0%
Sampson	64	0.5%	65	0.5%	66	0.5%
Scotland	18	0.1%	18	0.1%	18	0.1%
Stanly	4	0.0%	4	0.0%	4	0.0%
Stokes	2	0.0%	2	0.0%	2	0.0%
Swain	0	0.0%	0	0.0%	0	0.0%
Transylvania	2	0.0%	2	0.0%	2	0.0%
Union	18	0.1%	18	0.1%	18	0.1%
Vance	127	1.0%	128	1.0%	130	1.0%
Wake	8,016	62.6%	8,099	62.6%	8,184	62.6%
Warren	41	0.3%	41	0.3%	42	0.3%
Washington	12	0.1%	12	0.1%	12	0.1%
Watauga	0	0.0%	0	0.0%	0	0.0%
Wayne	119	0.9%	120	0.9%	122	0.9%
Wilkes	6	0.0%	6	0.0%	6	0.0%
Wilson	156	1.2%	158	1.2%	160	1.2%
Yadkin	0	0.0%	0	0.0%	0	0.0%
Yancy	0	0.0%	0	0.0%	0	0.0%
Out of State	543	4.2%	549	4.2%	554	4.2%
<b>Total # of Scans</b>	<b>12,813</b>	<b>100.0%</b>	<b>12,945</b>	<b>100.0%</b>	<b>13,081</b>	<b>100.0%</b>



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 remain consistent with the year-to-date 2024 utilization patterns of its existing MRI services. The applicant states it does not anticipate a change in its utilization trends by geography.

### **Analysis of Need**

In Section C, pages 36-39, 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 2024 SMFP for a fixed MRI scanner in Wake County.
- Wake County's population is projected to grow 20% over the course of this decade, with almost a quarter million new residents, further driving need for hospital services including MRI imaging.
- DUHS's growth in MRI volumes reflect growth of more than 40% between FY 2019 and FY 2023 in overall MRI utilization at DUHS facilities in Wake County.
- Due to the high and growing MRI utilization on the Duke Raleigh Hospital campus, DUHS has had to rely on a mobile MRI scanner with a third party provider for several years to mitigate capacity constraints.
- Duke Health's provider network and patient network has also grown steadily and now cares for nearly 150,000 unique patients in Wake County alone, and over 330,000 unique patients across the extended service area. This reflects a growth of more than 25% in Wake County between FY 2019 and FY 2023.
- The number of providers referring patients for MRI procedures at Duke Raleigh Hospital has increased to 1,100 different providers. This reflects a 9% increase in referring providers between June-December 2023.

### **Projected Utilization**

In Section Q, Forms C.2b, the applicant provides projected utilization for the first three full fiscal years, FYs 2027-2029 (07/1-06/30), for all of its fixed and mobile MRI scanners in Wake County as illustrated in the tables below:

Duke Raleigh Hospital Projected Utilization-Fixed MRI Services			
	1 <sup>ST</sup> FULL FY FY 2027	2 <sup>ND</sup> FULL FY FY 2028	3 <sup>RD</sup> FULL FY FY 2029
Number of Units	3	3	3
# Procedures (unadjusted)	15,165	15,322	15,482
# Adjusted Procedures	18,921	19,117	19,316

Duke Imaging Holly Springs Projected Utilization-Fixed MRI			
	1 <sup>ST</sup> FULL FY FY 2027	2 <sup>ND</sup> FULL FY FY 2028	3 <sup>RD</sup> FULL FY FY 2029
Number of Units	1	1	1
# Procedures (unadjusted)	3,135	3,181	3,226
# Adjusted Procedures	3,414	3,464	3,513

Duke Imaging Projected Utilization-Mobile MRI			
	1 <sup>ST</sup> FULL FY FY 2027	2 <sup>ND</sup> FULL FY FY 2028	3 <sup>RD</sup> FULL FY FY 2029
Number of Units	1	1	1
# Procedures (unadjusted)	3,809	4,058	4,058
# Adjusted Procedures	4,149	4,421	4,421

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

**Step 1:** The applicant provided historical volumes for its two fixed MRI scanners and one mobile MRI scanner operated on the hospital campus. DRAH currently operates one fixed MRI scanner in the main hospital building and a second in an outpatient clinic on the hospital’s campus.

**Step 2:** The applicant calculated DRAH MRI volume projections by applying anticipated population growth rates to FY2024 DRAH annualized volumes at the ZIP code level. The applied population growth rates are based on growth projections for the years 2024 through 2029. Compounded annual population growth rates for ZIP codes in North Carolina range from -1.8% to 3.2%, resulting in projected cumulative growth rate of approximately 1% per year

**Step 3:** The applicant adjusted its projections to account for a shift of volume to other DUHS imaging sites in and near the proposed service area that are new and/or under development and therefore are continuing to experience a ramp-up in volume. The cumulative shift of volume and the resulting utilization at DRAH are illustrated in the table below.

<b>Shifted Volumes</b>	<b>2025</b>	<b>2026</b>	<b>2027</b>	<b>2028</b>	<b>2029</b>
Shift to Holly Springs Outpatient (OP)	108	110	111	113	115
Shift to Knightdale (OP)	317	321	325	329	333
Shift to Arringdon (OP)	262	265	268	271	274
Total Shift from DRAH to Other Sites	687	695	704	713	722
Remaining DRAH MRI Volume after Projected Shift to Other Sites	14,859	15,011	15,165	15,322	15,482

Source: Section Q, page 92

**Step 4:** The applicant allocated a portion of the projected total MRI volume between the fixed and mobile scanners for FY 2025 and the first half of FY 2026 consistent with historical allocation and respective capacity. The applicant assumes that this projected volume can be accommodated on the fixed scanners when the third scanner is operational as of January 1, 2026. Adjusted procedures on the DRAH fixed scanners were projected based on the procedure mix for FY 2024 YTD/annualized.

**Step 5:** The applicant projects organic growth at Duke Imaging Holly Springs of 1.4% per year, based on the projected population growth rate in the ZIP codes within a 20-30 minute drive time of that facility. The applicant projects and applies a shift of volume from DRAH to Holly Springs as that facility’s MRI scanner utilization continues to ramp up. The applicant applies an adjustment factor for complex scans of 1.21 based on the facility’s FY 2024 year to date procedure mix.

**Step 6:** The applicant projects total fixed MRI utilization for DUHS Wake County scanners as illustrated in the table below.

<b>Total DUHS Wake County Fixed MRI Utilization/Adjusted</b>	<b>FY2024 Annualized</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>	<b>FY2029</b>
Holly Springs	3,109	3,318	3,366	3,414	3,464	3,515
DRAH	14,527	13,798	16,323	18,921	19,117	19,316
Total Procedures	17,636	17,116	19,689	22,335	22,581	22,829
Total Machines	3	3	4	4	4	4
Adjusted Procedures/Machine	5,879	5,705	4,922	5,584	5,645	5,707

Source: Section Q, page 95

**Step 7:** The applicant projects total mobile MRI utilization projected for DUHS Wake County scanners based on its volumes reported in its previously-approved application, as illustrated in the table below.

DUHS Mobile MRI Scanner Projected Utilization						
Days/Week	Site	FY2025	FY2026	FY2027	FY2028	FY2029
0.5	Mebane	122	335	432	445	445
0.5	Knightdale	135	332	396	404	404
4	Heritage	1,000	2,000	2,200	2,400	2,400
1	Duke Raleigh Hospital	368	757	781	809	809
<b>Total Unadjusted</b>		1,625	3,423	3,809	4,058	4,058
<b>Total Adjusted</b>		1,770	3,729	4,149	4,421	4,421

Source: Section Q, page 96

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

- There is a need determination in the 2024 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 on its existing fixed MRI scanners and the mobile scanner operated at DRAH, projected population growth and projected shift to its other MRI services’ sites.
- The applicant uses an annual growth rate for unadjusted MRI procedures at DRUH that is lower than its historical growth rate.
- The applicant uses a growth rate for unadjusted MRI procedures at its Holly Springs location that is lower than the projected compound annual growth rate projected for the population of Wake County, FY2020-FY2030.<sup>1</sup>
- 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 3,120 adjusted MRI procedures in the third full fiscal year of operation following project completion, as required by 10A NCAC 14C .2703(a)(8).

**Access to Medically Underserved Groups**

In Section C, page 44, the applicant states:

*“The services of Duke University Health System facilities, including Duke Raleigh Hospital, are open to all area and non-area residents. The hospital meets ADA requirements for accessibility to disabled persons. There is no discrimination on the basis of race, ethnicity, age, gender, or disability.”*

<sup>1</sup> <https://www.osbm.nc.gov/facts-figures/population-demographics/state-demographer/countystate-population-projections/population-growth-2020-2030>

The applicant provides additional information on page 44 of the application. On page 44, 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*	9.1%
Racial and ethnic minorities	37.4%
Women	63.5%
Persons with disabilities**	--
Persons 65 and older	44.7%
Medicare beneficiaries	44.7%
Medicaid beneficiaries	7.3%

\*The applicant states on page 44 that this category reflects the percentage of Medicaid and self-pay patients.

\*\* The applicant states on page 44 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 it has a robust financial assistance policy and provides significant services to low-income persons.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

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

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

the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Increase MRI capacity at another location– The applicant considered developing a new MRI at another location in Wake County. While it believes that demand for DUHS imaging services exists at other locations, the significant growth and capacity constraints at the hospital make this location the most urgent to meet current patient needs. Thus, the applicant states this is not the most effective alternative.
- Maintain/Increase mobile services – The applicant already contracts with Alliance Imaging for mobile MRI services at Duke Raleigh Hospital. DUHS may have the ability to continue or expand mobile MRI services if it does not have fixed capacity to meet the need for patients. However, mobile capacity is not as effective as full-time fixed capacity given its costs, limited hours of operation, and accessibility. Thus, the applicant states an alternative location is not the most effective alternative to meet patient needs.

On page 54, the applicant states that its proposal is the most effective alternative because it will be able to address the most urgent patient needs at its proposed location, upfit shell space, take advantage of shared support staff and services, and address scheduling delays.

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 is already providing imaging and ambulatory surgical services on the Duke Raleigh Hospital campus and adding fixed MRI capacity is a reasonable addition to the facility, given the current utilization of its existing MRI services.

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

### **Conclusion**

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. Duke University Health System, Inc., (hereinafter certificate holders) 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 2024 SMFP to be located at Duke Raleigh Hospital.**
- 3. Upon completion of the project, Duke Raleigh Hospital shall be licensed for no more than three fixed MRI scanners.**
- 4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holders shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**

- c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. **The first progress report shall be due on March 1, 2025.**
  - 6. **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.**
  - 7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

**Capital and Working Capital Costs**

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

Construction Costs	\$2,173,679
Architect/ Engineering Fees	\$590,000
Medical Equipment	2,800,000
Non-Medical Equipment	\$170,000
Furniture	\$100,000
Contingency Costs	\$1,167,321
<b>Total</b>	<b>\$7,001,000</b>

In Section Q, Form F.1 assumptions, page 97, 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:



- Non-medical and miscellaneous costs, including information systems and security, are based on the experience of DUHS, the parent entity, with similar projects.
- In Exhibit F.1(b), the applicant provides an equipment quote for the proposed MRI scanner.
- In Exhibit F.1(a), the applicant provides a construction cost estimate signed by the project architect which includes a cost breakdown that matches the construction cost listed on Form F.1a.

In Section F.3, pages 57-58, the applicant projects start-up costs for the proposed project as \$58,000. On page 58, 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 adequately supported assumptions based on the following:

- The applicant identifies the types of costs included in the start-up costs.
- The applicant provides a detailed line item breakdown of the start-up costs, including staff wages/salaries, ACR accreditation, equipment training, and contingency.

### **Availability of Funds**

In Section F, page 56, the applicant states the capital cost will be funded through the accumulated reserves of DUHS.

Exhibit F.2(a) contains a letter dated May 31, 2024, and signed by the Senior Vice President and Chief Financial Officer for DUHS, which commits to funding the capital cost from accumulated reserves of DUHS. Exhibit F.2(b) contains the most recent DUHS audited financial statements documenting the availability of the necessary funds.

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

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

### **Financial Feasibility**

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

June 30, following project completion. The following table shows the projections for fixed MRI services:

DUKE RALEIGH HOSPITAL FIXED MRI SERVICES			
MRI SERVICES ONLY^	1 <sup>ST</sup> FY	2 <sup>ND</sup> FY	3 <sup>RD</sup> FY
	07/1/26-06/30/27	07/1/27-06/30/28	07/1/28-06/30/29
# of Scans (Adjusted)^	18,921	19,117	19,316
Gross Revenue	\$63,619,466	\$64,278,104	\$64,949,328
Net Revenue	\$17,252,586	\$18,010,783	\$18,805,953
Average Net Revenue per Adjusted MRI Scan	\$912	\$942	\$974
Operating Costs	\$6,859,798	\$7,087,386	\$6,868,919
Average Operating Costs per Adjusted MRI Scan	\$363	\$371	\$356
Net Income	\$10,392,788	\$10,923,397	\$11,937,034

^Source: Section Q, Form F.2b

^^Source: Section Q, Form C.2b

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

- The applicant explains how it accounts for projected operating expenses and explains its revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately demonstrates that the capital cost and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.

- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs and working 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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

The 2024 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 15E-1, pages 352-353 of the 2024 SMFP:

**Wake County Fixed MRI Scanners**

PROVIDER/OWNER	# OF FIXED SCANNERS	SERVICE TYPE	TOTAL MRI SCANS	ADJUSTED TOTAL
Duke Raleigh Hospital	2	Hospital Fixed	10,572	13,492
UNC Health Rex	2	Hospital Fixed	7,797	11,024
UNC Rex Health Care of Cary	1	Hospital Fixed	0	0
WakeMed Cary Hospital	1	Hospital Fixed	4,630	6,197
WakeMed Raleigh Hospital	2	Hospital Fixed	10,839	15,506
Cardinal Points Imaging of the Carolinas Midtown / Pinnacle Health Services of North Carolina, LLC	1	Freestanding Fixed	4,097	4,441
2023 Need Determination	1	Freestanding Fixed	0	0
Duke Imaging Holly Springs / DUHS	1	Freestanding Fixed	2,579	2,792
EmergeOrtho Duraleigh	1	Freestanding Fixed	3,938	4,028
Raleigh Neurology Associates, P.A.	1	Freestanding Fixed	4,614	5,028
Raleigh Neurology Imaging, PLLC / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	4,932	5,427
Raleigh Radiology Blue Ridge	1	Freestanding Fixed	6,308	6,731
Raleigh Radiology Cary	1	Freestanding Fixed	6,243	6,716
The Bone and Joint Surgery Clinic	1	Freestanding Fixed	2,274	2,330
Wake Radiology / (WR Imaging)	1	Freestanding Fixed	3,766	4,122
Wake Radiology	1	Freestanding Fixed	4,294	4,634
Wake Radiology Cary	1	Freestanding Fixed	5,023	5,460
Wake Radiology Garner	1	Freestanding Fixed	3,799	4,173

Source: 2024 SMFP, Table 15-E1, pages 352-353

In Section G, page 64, 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. On page 64 the applicant states:

*“The State Medical Facilities Plan has recognized a need for an additional fixed MRI scanner in Wake County based on the utilization of the existing and approved inventory. As set forth in greater detail in Section C, additional capacity is needed to accommodate the high existing utilization at Duke Raleigh Hospital. Even as DUHS and other providers have developed services elsewhere in the county, utilization at this location has continued to grow faster than the county as a whole. Expanding capacity to meet the demand for the facility’s patients will therefore not unnecessarily duplicate any services provided elsewhere in the county, including services provided by DUHS at its off-campus locations.”*

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 2024 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

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

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

<b>Duke Raleigh Hospital Staffing MRI Services</b>				
<b>Position</b>	<b>Current Staff as of 6/30/2023</b>	<b>1<sup>st</sup> Full FY FY 2027</b>	<b>2nd Full FY FY 2028</b>	<b>3rd Full FY FY 2029</b>
MR Technologists	12.09	14.67	14.67	14.67
Radiology Supervisor	1.00	1.00	1.00	1.00
Clinical Nurse	0.00	1.68	1.68	1.68
Financial Care Counselor	0.00	1.68	1.68	1.68
Orientees	0.61	0.00	0.00	0.00
<b>Total</b>	<b>13.70</b>	<b>19.03</b>	<b>19.03</b>	<b>19.03</b>

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 65-66, 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 already provides fixed MRI services on the hospital campus and has experience in hiring and training staff for the provision of MRI services.
- The applicant adequately demonstrates its methods to train and retain staff, as well as provide continuing education.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

### **Ancillary and Support Services**

In Section I, page 67, 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 adequately demonstrates that the necessary ancillary and support services will be made available because MRI services are currently provided on the hospital campus with all necessary ancillary and support services.

### **Coordination**

In Section I, page 68, the applicant describes its existing relationships with other local health care and social service providers and states,

*“DUHS is a longstanding existing healthcare system in North Carolina and collaborates with other local health care and social service providers. Duke University Health System, along with Duke Health, works within the communities it serves to promote wellness and access to care. Partnering with residents, DUHS addresses*

*pressing needs to ensure healthy North Carolinians. In addition, through its DRAH, DUH, and DRH, DUHS cooperates with public health departments in Wake and Durham counties and numerous community organizations to better understand the needs of the people who live here. Duke physicians donate emergency, primary and specialty care services to eligible, uninsured patients through Project Access, a program in Durham and Wake counties. DUHS and its local partners continue collaborative efforts to eliminate healthcare disparities and to improve access to high-quality medical care.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant currently provides MRI scanner services at DRAH and will continue to do so following the development of the proposed project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

In Section K, page 70, the applicant states the project involves renovating 4,129 square feet of existing, unoccupied shell space in an outpatient clinic building on the DRAH campus. Line drawings are provided in Exhibit K.2.

On pages 70-71, 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 71, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that any costs incurred by it to develop and operate this facility are necessary and appropriate to provide critical screening and diagnostic services for patients in the area.
- The applicant states the project will not increase charges or projected reimbursement for the proposed services.

On page 71, 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
- Remarks made at the public hearing
- Responses to comments

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

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

C

In Section L, page 74, the applicant provides the historical payor mix during FY 2023 for its existing fixed MRI services at Duke Raleigh Hospital, as shown in the table below:

DUKE RALEIGH HOSPITAL HISTORICAL PAYOR MIX, FY 2023	
PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	1.4%
Charity Care	2.1%
Medicare	48.0%
Medicaid	7.9%
Insurance	37.6%
Workers Compensation	<1.0%
TRICARE	<1.0%
Other	<1.0%
<b>Total</b>	<b>100.0%</b>

Source: Section L, page 74

In Section L, page 75, 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	62.2%	50.9%
Male	37.8%	49.1%
Unknown	--	--
64 and Younger	54.9%	87.0%
65 and Older	45.1%	13.0%
American Indian	0.5%	0.8%
Asian	3.1%	8.9%
Black or African American	26.3%	20.8%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	62.3%	58.3%
Other Race	3.4%	2.8%
Declined / Unavailable	4.3%	--

United States Census Bureau's QuickFacts <https://www.census.gov/quickfacts/fact/table/US/PST045218>

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 76, the applicant states it has no such obligation.

In Section L, page 77, the applicant states that no patient civil rights equal access complaints have been filed against Duke Raleigh Hospital in the 18 months immediately preceding the application deadline.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 78, the applicant projects the following payor mix for Duke Raleigh Hospital MRI services during the third full fiscal year of operation following completion of the project, as shown in the table below:

<b>Duke Raleigh Hospital Fixed MRI Services Projected Payor Mix, FY 2029</b>	
<b>PAYOR CATEGORY</b>	<b>MRI SERVICES AS % OF TOTAL</b>
Self-Pay	1.8%
Charity Care	0.9%
Medicare	44.7%
Medicaid	7.3%
Insurance	42.3%
Workers Compensation	0.2%
TRICARE	1.3%
Other	1.4%
<b>Total</b>	<b>100.00%</b>

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.8% of MRI services provided by Duke Raleigh Hospital will be provided to self-pay patients, and 44.7% and 7.3% of total MRI services will be provided to Medicare and Medicaid patients, respectively.

On page 78, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the

project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical FY2024 payor mix for Duke Raleigh Hospital's MRI services with reasonable adjustments for aging into Medicare and a conservative estimate of shift from self-pay to Medicaid due to Medicaid expansion.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 79, the applicant adequately describes the range of means by which a person will have access to the proposed additional fixed MRI services at Duke Raleigh Hospital.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

In Section M, page 81, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant states that DRAH serves as a training site for clinical training rotations for DUHS healthcare

professionals and for students from area community colleges. The applicant adequately demonstrates that health professional training programs in the area have and will continue to have access to the facility for training purposes because the facility serves as a primary training location for healthcare professionals in the service area.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

The 2024 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 15E-1, pages 352-353 of the 2024 SMFP:

**Wake County Fixed MRI Scanners**

PROVIDER/OWNER	# OF FIXED SCANNERS	SERVICE TYPE	TOTAL MRI SCANS	ADJUSTED TOTAL
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UNC Health Rex	2	Hospital Fixed	7,797	11,024
UNC Rex Health Care of Cary	1	Hospital Fixed	0	0
WakeMed Cary Hospital	1	Hospital Fixed	4,630	6,197
WakeMed Raleigh Hospital	2	Hospital Fixed	10,839	15,506
Cardinal Points Imaging of the Carolinas Midtown / Pinnacle Health Services of North Carolina, LLC	1	Freestanding Fixed	4,097	4,441
2023 Need Determination	1	Freestanding Fixed	0	0
Duke Imaging Holly Springs / DUHS	1	Freestanding Fixed	2,579	2,792
EmergeOrtho Durableigh	1	Freestanding Fixed	3,938	4,028
Raleigh Neurology Associates, P.A.	1	Freestanding Fixed	4,614	5,028
Raleigh Neurology Imaging, PLLC / Alliance Healthcare Services, Inc.	1	Freestanding Fixed	4,932	5,427
Raleigh Radiology Blue Ridge	1	Freestanding Fixed	6,308	6,731
Raleigh Radiology Cary	1	Freestanding Fixed	6,243	6,716
The Bone and Joint Surgery Clinic	1	Freestanding Fixed	2,274	2,330
Wake Radiology / (WR Imaging)	1	Freestanding Fixed	3,766	4,122
Wake Radiology	1	Freestanding Fixed	4,294	4,634
Wake Radiology Cary	1	Freestanding Fixed	5,023	5,460
Wake Radiology Garner	1	Freestanding Fixed	3,799	4,173

Source: 2024 SMFP, Table 15-E1, pages 352-353

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 82, the applicant states:

*“This project will expand access and ease capacity constraints for highly utilized services at Duke Raleigh Hospital. Without additional capacity, the ability to timely meet the demand for these services is impeded, limiting patient and provider options for needed clinical care. This project will allow Duke Raleigh Hospital to continue to ensure meaningful patient and provider choice.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 82, the applicant states:

*“The cost to patients and payors is established by government and/or contractual rates and is not projected to change based on the addition of incremental equipment. However, to the extent that this project will reduce any delay in beginning treatment, it could decrease overall costs to patients and payors.”*

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

Regarding the impact of the proposal on quality and access by medically underserved groups, in Section N, page 82, the applicant states:

*“This project will have a positive impact on access and quality as a result of increasing the availability capacity for these heavily utilized hospital services. The existing MRI equipment is reaching capacity constraints which can affect the scheduling of procedures. Expanding capacity will increase scheduling flexibility and reduce any delays in treatment... DUHS is an established provider with a national reputation for high quality care, which will be expanded with this project.”*

See also Sections B, C, L and O 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
- Remarks made at the public hearing
- Responses to comments

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.

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2024 need determination for a total of no more than three fixed MRI scanners upon project completion.

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity providing MRI services. The applicant identifies a total of four of this type of facility located in North Carolina.

In Section O, page 86, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to the quality of care occurred in any of these facilities. 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, one incident occurred in each of two of the applicant's facilities, however both facilities are back in compliance. 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.

(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

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;*

-C- In Section C, page 46, the applicant states it currently owns or operates three 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- As of the first day of the review period for this review, neither the applicant or a related entity has approved fixed MRI scanners owned or operated 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;*
- C- In Section C, page 46, the applicant states it owns and operates a mobile MRI scanner that began providing services on June 1, 2024. This MRI scanner was approved to provide services at two locations in Wake County, Knightdale and Wake Forest/Heritage.
- (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- Neither the applicant, nor a related entity has approved mobile MRI scanners that will be operated at host sites 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- 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.
- (6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;*
- C- In Section Q, pages 90-96 “Assumptions”, the applicant provides the assumptions and methodology used to project utilization of its existing and proposed fixed MRI scanners.
- (7) *project that the fixed MRI scanners identified in Subparagraphs (1) and (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) *3,494 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) 3,058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or
- (c) 1,310 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 15E-1, pages 352-353 of the 2024 SMFP, there are currently 21 existing fixed MRI scanners in the Wake County fixed MRI scanner service area and two additional fixed MRI scanners for which there were Agency approvals, however both of those decisions are currently under appeal. Therefore, Subparagraph (a) applies to this review.

- C- In Section Q, Form C.2b, 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, as shown in the table below. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

<b>Total DUHS Wake County Fixed MRI Utilization/Adjusted</b>	<b>FY2024 Annualized</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>	<b>FY2029</b>
Holly Springs	3,109	3,318	3,366	3,414	3,464	3,515
DRAH	14,527	13,798	16,323	18,921	19,117	19,316
Total Procedures	17,636	17,116	19,689	22,335	22,581	22,829
Total Machines	3	3	4	4	4	4
Adjusted Procedures/Machine	5,879	5,705	4,922	5,584	5,645	5,707

Source: Section Q, page 95

- (8) *Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3,120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of operation following completion of the proposed project.*
- C- The applicant relies on the projections approved in Project J-12378-23 to forecast volume for the mobile MRI scanner as it has only begun services just prior to submission of this application.

DUHS Mobile MRI Scanner Projected Utilization						
Days/Week	Site	FY2025	FY2026	FY2027	FY2028	FY2029
0.5	Mebane	122	335	432	445	445
0.5	Knightdale	135	332	396	404	404
4	Heritage	1,000	2,000	2,200	2,400	2,400
1	Duke Raleigh Hospital	368	757	781	809	809
<b>Total Unadjusted</b>		1,625	3,423	3,809	4,058	4,058
<b>Total Adjusted</b>		1,770	3,729	4,149	4,421	4,421

Source: Section Q, page 96

- (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 (1) and (2) of this Paragraph and the proposed mobile MRI scanner;*
  - (6) *provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (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 (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 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operation 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) *3,494 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) 3,058 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;*
- (C) 1,310 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;*

-NA- 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.