

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 28, 2024

Findings Date: April 4, 2024

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: J-12436-23

Facility: Duke University Hospital

FID #: 943138

County: Durham

Applicant(s): Duke University Health System, Inc.

Project: Acquire no more than one fixed MRI scanner pursuant to the 2023 SMFP need determination

### 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. (Hereinafter referred to as “the applicant” or “DUHS”) proposes to acquire no more than one fixed MRI scanner pursuant to the 2023 SMFP need determination. The applicant is proposing to locate the fixed MRI scanner on the Duke University Hospital (“DUH”) main campus.

According to the 2023 SMFP, DUHS owned and operated 13 fixed MRI scanners in Durham County; nine located on the DUH main campus, one located at the DUH Southpoint Clinic (“Southpoint”), two at Duke Regional Hospital (DRH), and one at Duke Imaging Arrington. In July 2023, one additional fixed MRI scanner became operational at Duke Imaging Arrington, for a total of 14 fixed MRI scanners owned and operated by the applicant in Durham County.

## **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 Durham County. The application was submitted in response to the need determination in the 2023 SMFP for one fixed MRI scanner in Durham County. Therefore, the application is consistent with the need determination in the 2023 SMFP.

## **Policies**

Two policies in Chapter 4 of the 2023 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 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.”*

In Section B, page 31, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states that the proposal will expand access to MRI services which can decrease wait time for specialized services and improve access to diagnostic imaging services necessary to coordinate services, thereby improving quality of care. DUH will continue to be accessible to all persons, including those in underserved groups, and will maximize healthcare value by increasing capacity that will reduce wait time for emergency patients and allow patients to moved to the next stage of care delivery.

### **Policy GEN-4**

Policy GEN-4 on page 30 of the 2023 SMFP states:

*“Any person proposing a capital expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 32, the applicant describes the project's plan to improve energy efficiency and water conservation. The applicant states,

*"DUHS will ensure the proposed MRI space will be renovated in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption, including 2023 SMFP Policy GEN-4. Construction will be pursued to ensure energy efficient fixtures. DUHS will closely monitor its utility usage and costs (including water utilization) in order to maintain efficient and environmentally responsible energy operations."*

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 based on the following:

- The applicant does not propose developing 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 and Policy GEN-4 based on the following:
  - The applicant adequately documents how the project will promote safety and quality in the delivery of fixed MRI services in Durham County.
  - The applicant adequately documents how the project will promote equitable access to fixed MRI services in Durham County.

- 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

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2023 SMFP need determination.

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

The following tables illustrate historical and projected patient origin for MRI services at DUH.

County	Duke University Hospital Fixed MRI Services Historical Patient Origin	
	Last Full FY 07/01/2022-06/30/2023	
	Patients	% of Total
Durham	12,358	25.8%
Wake	6,687	13.9%
Orange	3,382	7.1%
Alamance	2,070	4.3%
Granville	1,394	2.9%
Person	1,203	2.5%
Cumberland	1,149	2.4%
Guilford	959	2.0%
Vance	815	1.7%
Franklin	529	1.1%
Johnston	523	1.1%
New Hanover	495	1.0%
Out of State	6,351	13.2%
Other*	10,020	20.9%
<b>Total</b>	<b>47,934</b>	<b>100.00%</b>

Source: Section C, page 34

\*Other Includes less than 1% patient origin from each remaining county in North Carolina.

Duke University Hospital Fixed MRI Services Projected Patient Origin						
County	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	7/1/25-6/30/26		7/1/26-6/30/27		7/1/27-6/30/28	
	FY2026		FY2027		FY2028	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Durham	12,595	25.8%	12,858	25.8%	13,140	25.8%
Wake	6,815	13.9%	6,957	13.9%	7,110	13.9%
Orange	3,446	7.1%	3,518	7.1%	3,596	7.1%
Alamance	2,109	4.3%	2,153	4.3%	2,201	4.3%
Granville	1,420	2.9%	1,450	2.9%	1,482	2.9%
Person	1,226	2.5%	1,252	2.5%	1,280	2.5%
Cumberland	1,171	2.4%	1,196	2.4%	1,222	2.4%
Guilford	977	2.0%	998	2.0%	1,020	2.0%
Vance	831	1.7%	848	1.7%	867	1.7%
Franklin	539	1.1%	550	1.1%	562	1.1%
Johnston	533	1.1%	544	1.1%	556	1.1%
New Hanover	505	1.0%	515	1.0%	527	1.0%
Out of State	6,472	13.2%	6,608	13.2%	6,753	13.2%
Other*	10,212	20.9%	10,425	20.9%	10,654	20.9%
<b>Total</b>	<b>48,851</b>	<b>100.0%</b>	<b>49,873</b>	<b>100.0%</b>	<b>50,968</b>	<b>100.0%</b>

Source: Section C, page 36

Other Includes less than 1% patient origin from each remaining county in North Carolina.

In Section C, page 36, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The projected patient origin is based on FY2023 patient origin percentages for the fixed MRI scanner service line on the DUH main campus.
- The applicant projects a two percent yearly increase of inpatient and outpatient encounters based on historical and projected population growth and its physician recruitment plans.

**Analysis of Need**

In Section C, pages 39-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

*2023 State Medical Facilities Plan Need Determination (pages 39-40)*

There is an increased demand for MRI services in Durham County, as demonstrated by the need for an additional fixed MRI scanner, as published in the 2023 SMFP.

*Statewide MRI Utilization (pages 40-41)*

North Carolina use rates have increased significantly in the most recent years. From 2017 to 2022, the statewide use rates increased by a Compound Annual Growth Rate (CAGR) of 1.8 percent. Moreover, the number of statewide MRI procedures increased by 2.7 percent. The increase in the statewide utilization rates demonstrates the need to expand MRI services at DUH. The applicant states that DUH serves MRI patients from all 100 North Carolina counties, including other states.

*Durham County Fixed MRI Scanner Utilization (pages 41-42)*

According to the Proposed 2024 SMFP, DUHS fixed MRI scanners performed the highest average adjusted procedures per unit and has exceeded the adjusted planning threshold of 4,992 procedures during FY2022. The proposal to enhance MRI capacity would be better served at a DUHS facility, particularly DUS because of the facility's volume of MRI procedures performed and the growth in inpatient MRI volumes.

*DUHS MRI Utilization (pages 42-45)*

DUHS existing fixed MRI scanners in the service area have experienced a significant growth in the number of procedures performed, further demonstrating the need to expand its fixed MRI capacity.

*Broad Referral Network and Growth in Duke Health Providers (page 45)*

The applicant states that Duke's primary care provider network has continued to grow as well as the network of specialty providers who refer patients for MRI imaging. As the provider network continues to grow, the need for imaging referrals will increase.

*Service Area Demographics (46-48)*

According to the North Carolina Office of State Budget Management (NCOSBM), the Durham County population is projected to grow by a CAGR of 1.3 percent between 2023-2028. The 65+ age group is projected to grow at the highest rate among other age cohorts during the same period. The applicant states that DUHS has historically served patients residing outside Durham County. During FY2023, approximately 74 percent of DUH's MRI patient origin was outside of Durham County. The population in Alamance, Granville, Orange, Person and Wake counties is projected to see an average CAGR of 1.1 percent which is consistent with the statewide projected population growth.

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

- There is a 2023 SMFP need determination for one fixed MRI scanner in Durham County.
- The applicant provides reliable information to support the need for fixed MRI services to serve based on the growing primary care and referring physician network.

- The applicant relied on data from NCOSBM to demonstrate the projected population growth and aging in Durham County that supports the need to expand MRI services.
- The growth in utilization of MRI procedures performed on the existing fixed MRI scanners owned and operated by the applicant and the historical growth in the statewide MRI use rate.

Projected Utilization

In Section Q, pages 103-108, the applicant provides historical and projected utilization, as illustrated in the following table(s).

<b>DUHS Fixed MRI Scanners Historical and Interim Utilization</b>			
	<b>Last Full FY FY2023</b>	<b>Interim Full FY FY2024</b>	<b>Interim Full FY FY2025</b>
<b>DUH &amp; Southpoint</b>			
# of Units	10	10	10
# of Procedures	47,934	49,030	50,063
# of Weighted Procedures	62,893	64,279	65,596
<b>Duke Regional Hospital</b>			
# of Units	2	2	2
# of Procedures	10,567	10,909	11,234
Weighted Procedures	13,665	14,042	14,401
<b>Duke Imaging Arrington</b>			
# of Units	2	2	2
# of Procedures	4,194	6,418	9,073
# of Weighted Procedures	4,457	6,820	9,642

<b>DUHS Fixed MRI Scanners Projected Utilization</b>			
	<b>1<sup>st</sup> Full FY FY2026</b>	<b>2<sup>nd</sup> Full FY FY2027</b>	<b>3<sup>rd</sup> Full FY FY2028</b>
<b>DUH &amp; Southpoint</b>			
# of Units	11	11	11
# of Procedures	50,885	51,933	53,060
# of Weighted Procedures	66,676	68,014	69,445
<b>Duke Regional Hospital</b>			
# of Units	2	2	2
# of Procedures	11,517	11,867	12,254
Weighted Procedures	14,713	15,099	15,526
<b>Duke Imaging Arrington</b>			
# of Units	2	2	2
# of Procedures	9,012	8,988	8,972
# of Weighted Procedures	9,576	9,551	9,534

In Section Q, pages 110-120, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*DUH Project MRI Utilization*

The applicant begins projections with the historical utilization of DUH’s nine fixed MRI scanners located on the main campus.

<b>Duke University Hospital Campus Fixed MRI Scanner Utilization</b>						
	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>	<b>19-23 CAGR</b>
IP MRI Procedures	9,254	8,812	8,986	9,420	9,883	1.7%
OP MRI Procedures	29,716	31,947	34,708	35,617	36,093	5.0%
<b>Unadjusted Total</b>	<b>38,970</b>	<b>40,759</b>	<b>43,694</b>	<b>45,037</b>	<b>45,976</b>	<b>4.2%</b>

Source: Section Q, page 110

The applicant projects that DUH’s inpatient MRI utilization will increase by the FY2019-FY2023 CAGR (1.7%) and the outpatient MRI utilization will increase by half the FY2019-FY2023 CAGR (2.5%). The applicant states that projections are supported by the projected population growth and aging in the service area, historical utilization of DUHS’ existing fixed MRI scanners and their growing physician network.



<b>Duke University Hospital Campus Fixed MRI Scanner Utilization</b>					
	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
IP MRI Procedures	10,047	10,213	10,383	10,555	10,730
OP MRI Procedures	36,992	37,913	38,857	39,825	40,816
<b>Unadjusted Total</b>	<b>47,039</b>	<b>48,126</b>	<b>49,240</b>	<b>50,379</b>	<b>51,546</b>

Source: Section Q, page 111

The applicant was approved in September 2023 (Project J-12378-23) for a mobile MRI scanner to serve Alamance, Durham and Wake counties. The applicant subtracts the MRI procedures projected to shift from DUH to the mobile MRI host sites in Alamance (Mebane) and Wake (Knightdale) counties. The discussion regarding projected utilization for the approved mobile MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke University Hospital Campus To DUHS Mobile MRI Host Sites</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Projected OP MRI Procedures	37,913	38,857	39,825	40,816
DUH MRI Procedures Projected to Shift to DUHS Mobile MRI at Mebane	60	164	210	215
DUH MRI Procedures Projected to Shift to DUHS Mobile MRI at Knightdale	21	52	62	63
<b>Remaining OP MRI Procedures at DUH</b>	<b>37,832</b>	<b>38,642</b>	<b>39,553</b>	<b>40,538</b>

Source: Section Q, page 111

The applicant submitted an application on June 15, 2023 (Project J-12395-23)<sup>1</sup> for one fixed MRI scanner in Wake County. The applicant subtracts the MRI procedures projected to shift from DUH to the proposed Wake County fixed MRI scanner to be located at Duke Imaging Garner. The discussion regarding projected utilization for the proposed Wake County fixed MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke University Hospital Campus To Duke Imaging Garner Project ID# J-12395-23</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Projected OP MRI Procedures	37,832	38,642	39,553	40,538
DUH MRI Procedures Projected to Shift to Duke Imaging Garner		173	235	300
<b>Remaining OP MRI Procedures at DUH</b>	<b>37,832</b>	<b>38,469</b>	<b>39,318</b>	<b>40,238</b>

Source: Section Q, page 111

The applicant projects the percentage of inpatient (IP) and outpatient (OP) MRI procedures involving contrast based on DUH's FY2023 historical experience.

<sup>1</sup> Project ID# J-12395-23 (2023 Wake MRI Competitive Review) was denied November 2023 and is currently under Appeal. The applicant submitted this application to the Agency on October 15, 2023. Although the application submitted by DUHS was denied, it was conforming or conditionally conforming to all applicable statutory and regulatory review criteria, including Criterion (3).

<b>Duke University Hospital Campus Projected Fixed MRI Utilization</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
IP w/ Contrast	5,908	6,006	6,105	6,207	6,310	6,414
IP w/o contrast	3,975	4,041	4,108	4,176	4,245	4,316
IP Total	9,883	10,047	10,213	10,383	10,555	10,730
OP w/ Contrast	23,566	24,153	24,701	25,117	25,672	26,273
OP w/o contrast	12,527	12,839	13,131	13,352	13,646	13,966
OP Total	36,093	36,992	37,832	38,469	39,318	40,238
<b>Unadjusted MRI Total</b>	<b>45,976</b>	<b>47,039</b>	<b>48,045</b>	<b>48,851</b>	<b>49,873</b>	<b>50,968</b>
<b>Adjusted MRI Total</b>	<b>60,851</b>	<b>62,202</b>	<b>63,492</b>	<b>64,555</b>	<b>65,866</b>	<b>67,264</b>

Source: Section Q, page 112

*DUH Southpoint Projected MRI Utilization*

The applicant begins its projections with the historical utilization of the fixed MRI scanner located at DUH’s Southpoint Clinic.

<b>Duke University Hospital Southpoint Fixed MRI Scanner Utilization</b>						
	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>	<b>19-23 CAGR</b>
OP MRI Procedures	1,830	1,471	1,827	1,855	1,958	1.7%

Source: Section Q, page 112

The applicant projects that Southpoint’s MRI utilization will increase by the historical growth rate of 1.7 percent. The applicant states that projections are reasonable because DUH regularly transfers a portion of its outpatient MRI utilization to Southpoint. Additionally, the applicant’s projected growth rate is significantly lower than DUHS’ FY2019-FY2023 CAGR outpatient MRI procedures in Durham County, as illustrated in Section C of the application.

<b>Duke University Hospital Southpoint Fixed MRI Scanner Utilization</b>					
	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
OP MRI Procedures	1,991	2,025	2,060	2,095	2,131

Source: Section Q, page 113

The applicant subtracts the MRI procedures projected to shift from Southpoint to the approved Alamance (Mebane) mobile MRI host site (Project ID# J-12378-23). The discussion regarding projected utilization for the approved mobile MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke University Hospital Southpoint To DUHS Mobile MRI Host Site</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Southpoint Projected OP MRI Procedures	2,025	2,060	2,095	2,131
DUH Southpoint MRI Procedures Projected to Shift to DUHS Mobile MRI at Mebane	7	20	27	28
<b>Remaining OP MRI Procedures at DUH-Southpoint</b>	<b>2,018</b>	<b>2,040</b>	<b>2,068</b>	<b>2,102</b>

Source: Section Q, page 113

The applicant subtracts the MRI procedures projected to shift from Southpoint to the proposed Wake County fixed MRI scanner to be located at Duke Imaging Garner (Project ID# J-12395-23<sup>2</sup>). The discussion regarding projected utilization for the proposed Wake County fixed MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke University Hospital Campus To Duke Imaging Garner Project ID# J-12395-23</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Southpoint Projected OP MRI Procedures	2,018	2,040	2,068	2,102
DUH Southpoint MRI Procedures Projected to Shift Duke Imaging Garner	N/A	6	8	10
<b>Remaining OP MRI Procedures at DUH Southpoint</b>	<b>2,018</b>	<b>2,034</b>	<b>2,060</b>	<b>2,092</b>

Source: Section Q, page 113

The applicant projects the percentage of outpatient MRI procedures involving contrast based on Southpoint's FY2023 historical experience.

<b>Duke University Hospital Southpoint Projected Fixed MRI Utilization</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
OP w/ contrast	395	402	407	410	416	422
OP w/o contrast	1,563	1,590	1,611	1,623	1,644	1,670
<b>Unadjusted MRI Total</b>	<b>1,958</b>	<b>1,991</b>	<b>2,018</b>	<b>2,034</b>	<b>2,060</b>	<b>2,092</b>
<b>Adjusted MRI Total</b>	<b>2,042</b>	<b>2,077</b>	<b>2,104</b>	<b>2,121</b>	<b>2,148</b>	<b>2,182</b>

Source: Section Q, page 114

*Duke Regional Hospital (DRH) Projected MRI Utilization*

The applicant begins projections with the historical utilization of the fixed MRI scanners located at DRH.

<sup>2</sup> Project ID# J-12395-23 (2023 Wake MRI Competitive Review) was denied November 2023 and is currently under Appeal. The applicant submitted this application to the Agency on October 15, 2023. Although the application submitted by DUHS was denied, it was conforming or conditionally conforming to all applicable statutory and regulatory review criteria, including Criterion (3).

<b>Duke Regional Hospital Fixed MRI Scanner Utilization</b>						
	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>	<b>19-23 CAGR</b>
IP MRI Procedures	2,444	2,304	2,586	2,208	2,391	-0.5%
OP MRI Procedures	6,939	6,167	6,920	7,785	8,176	4.2%
<b>Unadjusted Total</b>	<b>9,383</b>	<b>8,471</b>	<b>9,506</b>	<b>9,993</b>	<b>10,567</b>	<b>3.0%</b>

Source: Section Q, page 114

The applicant projects that inpatient MRI utilization will remain constant and outpatient MRI utilization will increase by the historical outpatient growth rate of 4.2 percent. The applicant states that its projections are supported by the projected population growth in the service area and the historical utilization of DUHS' existing fixed MRI scanners and their growing physician network. The applicant's projected growth rate is significantly lower than DUHS' FY2019-FY2023 CAGR for outpatient MRI procedures in Durham County, as illustrated in Section C of the application.

<b>Duke Regional Hospital Fixed MRI Scanner Utilization</b>					
	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
IP MRI Procedures	2,391	2,391	2,391	2,391	2,391
OP MRI Procedures	8,518	8,875	9,246	9,634	10,037
<b>Unadjusted Total</b>	<b>10,909</b>	<b>11,266</b>	<b>11,637</b>	<b>12,025</b>	<b>12,428</b>

Source: Section Q, page 114

The applicant subtracts the MRI procedures projected to shift from DRH to the approved Alamance (Mebane) and Wake (Knightdale) mobile MRI host sites (Project ID# J-12378-23). The discussion regarding projected utilization for the approved mobile MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>Outpatient MRI Procedures Projected to Shift from DRH To DUHS Mobile MRI Host Sites</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DRH Projected OP MRI Procedures	8,875	9,246	9,634	10,037
DRH MRI Procedures Projected to Shift to DUHS Mobile MRI at Mebane	9	81	104	108
DRH MRI Procedures Projected to Shift to DUHS Mobile MRI at Knightdale	2	6	7	7
<b>Remaining OP MRI Procedures at DRH</b>	<b>8,843</b>	<b>9,160</b>	<b>9,522</b>	<b>9,921</b>

Source: Section Q, page 115

The applicant subtracts the MRI procedures projected to shift from DRH to the proposed Wake County fixed MRI scanner to be located at Duke Imaging Garner (Project ID# J-12395-23<sup>3</sup>). The discussion regarding projected utilization for the approved Wake County fixed MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from DRH To Duke Imaging Garner Project ID# J-12395-23</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DRH Projected OP MRI Procedures	8,843	9,160	9,522	9,921
DRH MRI Procedures Projected to Shift to Duke Imaging Garner	N/A	34	46	59
<b>Remaining OP MRI Procedures at DRH</b>	<b>8,843</b>	<b>9,126</b>	<b>9,476</b>	<b>9,863</b>

Source: Section Q, page 115

The applicant projects the percentage of inpatient and outpatient MRI procedures involving contrast based on DRH's FY2023 historical experience.

<b>Duke Regional Hospital Fixed MRI Utilization</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
IP w/ Contrast	976	976	976	976	976	976
IP w/o contrast	1,415	1,415	1,415	1,415	1,415	1,415
IP Total	2,391	2,391	2,391	2,391	2,391	2,391
OP w/ Contrast	3,987	4,154	4,312	4,450	4,621	4,809
OP w/o contrast	4,189	4,364	4,531	4,676	4,855	5,053
OP Total	8,176	8,518	8,843	9,126	9,476	9,863
<b>Unadjusted MRI Total</b>	<b>10,567</b>	<b>10,909</b>	<b>11,234</b>	<b>11,517</b>	<b>11,867</b>	<b>12,254</b>
<b>Adjusted MRI Total</b>	<b>13,665</b>	<b>14,042</b>	<b>14,401</b>	<b>14,713</b>	<b>15,099</b>	<b>15,526</b>

Source: Section Q, page 116

*Duke Imaging Arrington MRI Utilization*

The applicant begins its projections with the historical utilization of the fixed MRI scanner located at Duke Imaging Arrington. The fixed MRI scanner became operational in May 2021 (Project ID# J-11718-19). The following historical utilization includes a swift ramp-up period.

<b>Duke Imaging Arrington Fixed MRI Scanner Utilization</b>			
	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>
MRI Procedures	1,048	2,941	4,191

Source: Section Q, page 117

<sup>3</sup> Project ID# J-12395-23 (2023 Wake MRI Competitive Review) was denied November 2023 and is currently under Appeal. The applicant submitted this application to the Agency on October 15, 2023. Although the application submitted by DUHS was denied, it was conforming or conditionally conforming to all applicable statutory and regulatory review criteria, including Criterion (3).

The facility was approved for a second fixed MRI scanner that became operational in July 2023 (Project ID# J-11913-20). The following table illustrates the applicant’s assumptions and methodology that were used to project utilization for both fixed MRI scanners.

<b>Duke Imaging Arrington Approved CON Projections for Two Fixed MRI Scanners</b>			
	<b>Project Year 1</b>	<b>Project year 2</b>	<b>Project Year 3</b>
Unweighted Scans-Total	<b>3,850</b>	<b>6,418</b>	<b>9,086</b>
Weighting Assumption	1.15	1.15	1.15
Weighted Scans-Total	7,132	10,189	10,445
# of MRI Scanners	2	2	2
Weighted Procedures/Scanner	3,566	5,095	5,223

Source: Section Q, page 117

The applicant applies the approved projected utilization of the two fixed MRI scanners from Project ID# J-11913-20 to project utilization for Duke Imaging Arrington. The applicant applied projections for the second project year (6,418) to FY2024 and applied projections for the third project year (9,086) to FY2025. The first three years (FY2026-FY2028) of the project are projected to remain consistent with FY2025.

<b>Duke Imaging Arrington MRI Scanner Utilization</b>					
	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
MRI Procedures	6,418	9,086	9,086	9,086	9,086

Source: Section Q, page 117

The applicant states that Duke Imaging Arrington projections are reasonable and adequately supported based on the following:

- Duke Imaging Arrington is the first non-hospital based imaging center in Durham County offering services at lower cost.
- Duke Imaging Arrington’s fixed MRI scanner experienced a quick ramp-up period.
- Continued growth in DUHS outpatient MRI volumes.
- The existing and approved MRI scanners are co-located with DUHS’ primary, specialty and surgical services.
- Population growth in the service area.
- Duke Imaging Arrington offers a broad range of MRI services.

The applicant subtracts the MRI procedures projected to shift from Duke Imaging Arrington to the approved mobile MRI host sites in Alamance, Durham and Wake counties (Project J-12378-23). The discussion regarding projected utilization for the approved mobile MRI scanners found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke Imaging Arrington To DUHS Mobile MRI Host Sites</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
Arrington Projected MRI Procedures	9,086	9,086	9,086	9,086
Arrington MRI Procedures Projected to Shift to DUHS Mobile MRI Host Sites	13	33	42	43
<b>Remaining MRI Procedures at Arrington</b>	<b>9,073</b>	<b>9,053</b>	<b>9,044</b>	<b>9,043</b>

Source: Section Q, page 118

The applicant subtracts the MRI procedures projected to shift from Duke Imaging Arrington to the proposed Wake County fixed MRI scanner to be located at Duke Imaging Garner (Project ID# J-12395-23<sup>4</sup>). The discussion regarding projected utilization for the approved Wake County fixed MRI scanner found in Exhibit Q is incorporated herein by reference.

<b>MRI Procedures Projected to Shift from Duke Imaging Arrington To Duke Imaging Garner Project ID# J-12395-23</b>				
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
Arrington Projected OP MRI Procedures	9,073	9,053	9,044	9,043
Arrington MRI Procedures Projected to Shift to Duke Imaging Garner	N/A	41	56	71
<b>Remaining OP MRI Procedures at Arrington</b>	<b>9,073</b>	<b>9,012</b>	<b>8,988</b>	<b>8,972</b>

Source: Section Q, page 118

The applicant projects the percentage of MRI procedures involving contrast based on Duke Imaging Arrington's FY2023 historical experience.

<b>Duke Imaging Arrington Fixed MRI Scanner Utilization</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
OP w/ Contrast	1,239	1,896	2,681	2,662	2,655	2,650
OP w/o contrast	2,955	4,522	6,393	6,349	6,333	6,321
<b>Unadjusted MRI Total</b>	<b>4,194</b>	<b>6,418</b>	<b>9,073</b>	<b>9,012</b>	<b>8,988</b>	<b>8,972</b>
<b>Adjusted MRI Total</b>	<b>4,457</b>	<b>6,820</b>	<b>9,642</b>	<b>9,576</b>	<b>9,551</b>	<b>9,534</b>

Source: Section Q, page 119

*Summary: DUHS Durham County fixed MRI Scanners*

<sup>4</sup> Project ID# J-12395-23 (2023 Wake MRI Competitive Review) was denied November 2023 and is currently under Appeal. The applicant submitted this application to the Agency on October 15, 2023. Although the application submitted by DUHS was denied, it was conforming or conditionally conforming to all applicable statutory and regulatory review criteria, including Criterion (3).

<b>Duke University Health System Fixed MRI Scanner Utilization: Durham County Unadjusted MRI Procedures</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Main	45,976	47,039	48,045	48,851	49,873	50,968
DUH Southpoint	1,958	1,991	2,018	2,034	2,060	2,092
DRH	10,567	10,909	11,234	11,517	11,867	12,254
Duke Imaging Arrington	4,194	6,418	9,073	9,012	8,988	8,972
<b>Total Unadjusted</b>	<b>62,695</b>	<b>66,357</b>	<b>70,371</b>	<b>71,414</b>	<b>72,788</b>	<b>74,286</b>

Source: Section Q, page 119

<b>Duke University Health System Fixed MRI Scanner Utilization: Durham County Adjusted MRI Procedures</b>						
	<b>FY2023</b>	<b>FY2024</b>	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>
DUH Main	60,851	62,202	63,492	64,555	65,866	67,264
DUH Southpoint	2,042	2,077	2,104	2,121	2,148	2,182
DRH	13,665	14,042	14,401	14,713	15,099	15,526
Duke Imaging Arrington	4,457	6,820	9,642	9,576	9,551	9,534
<b>Total Adjusted</b>	<b>81,015</b>	<b>85,141</b>	<b>89,639</b>	<b>90,965</b>	<b>92,665</b>	<b>94,505</b>

Source: Section Q, page 120

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

- There is a 2023 SMFP need determination for one fixed MRI scanner in Durham County.
- The applicant’s projections are supported by the projected growth and aging of the service area population and DUHS’ broad referral network and growth in primary care providers.
- The applicant relied on the historical utilization of the existing fixed MRI scanners owned and operated by DUHS to project future utilization.
- The applicant reasonably projects a shift of MRI procedures from DUHS’ existing fixed MRI scanners to the approved and proposed MRI scanners based on the approved assumptions and methodology used to project fixed and mobile MRI utilization.<sup>5</sup>

**Access to Medically Underserved Groups**

In Section C, page 53, 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 DUH’s MRI services, as clinically appropriate. DUHS does not and will not discriminate based on*

<sup>5</sup> Although Project ID# J-12395-23 (2023 Wake MRI Competitive Review) was denied in November 2023 and remains on appeal, the projected shift to and from the proposed Wake County MRI scanner are minimal. Even if Project ID# J-12395-23 is ultimately denied upon further appeal, the applicant’s application is conforming with Criterion (3).



*race, ethnicity, age, gender, disability, or sexual orientation. Policies to provide access to services by low-income, medically indigent, uninsured, or underinsured patients are described and provided in Exhibits C.6 and L.4.”*

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

<b>DUHS 3<sup>rd</sup> Full FY, FY2027</b>	
<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	14.10%
Racial and ethnic minorities	38.86%
Women	58.91%
Persons with Disabilities*	
Persons 65 and older	36.56%
Medicare beneficiaries	39.30%
Medicaid recipients	11.50%

Source: Section C, page 54

\*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:

- DUH service area consists of Durham County, however, the facility has served residents from all 100 counties in North Carolina and has historically provided services to those defined as underserved.
- In Exhibits C.6 and L.4, the applicant provides policies regarding access to services by low-income, medically indigent, uninsured, or underinsured patients

### **Conclusion**

The Agency reviewed the:

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

- (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 2023 SMFP need determination.

In Section E, pages 65-66, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

**Add MRI Capacity at Another Location-**The applicant considered adding the proposed fixed MRI scanner at one of the other locations, however, this alternative would not provide the much needed capacity for DUH's emergency or inpatient MRI procedures. Also, adding the MRI to another location would require new construction which would be more costly and take longer to implement.

**Contract for Mobile MRI Services-**The applicant states that the vendor has not been able to increase the days of service at other locations of the existing mobile services. A mobile MRI will not alleviate capacity at DUH because the scanner does not operate on a 24/7 schedule and is limited to outpatient procedures. Additionally, the hospital does not have space available to accommodate a mobile MRI scanner. Constructing a new space can incur significant costs.

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

- The applicant's proposal to locate the fixed MRI scanner in a readily available space on the DUH campus will expand capacity for emergency and inpatient MRI procedures.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. 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 2023 SMFP to be located at Duke University Hospital main campus.**
  - 3. Upon completion of the project, Duke University Hospital shall be licensed for no more than 11 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 August 1, 2024.**
  - 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 2023 SMFP need determination.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 2, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Duke University Hospital Projected Capital Cost</b>	
Construction/Renovation Contract(s)	\$2,000,000
Architect/Engineering Fees	\$150,000
Medical Equipment	\$3,500,000
Non-Medical Equipment	\$50,000
Furniture	\$30,000
Other (contingency)	\$450,000
<b>Total</b>	<b>\$6,180,000</b>

In Section Q, page 123, 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 applicant projects construction cost based on the architect’s estimate and projects the cost of the MRI scanner based on the vendor’s quote.
- All other costs are based on DUHS’ experience with similar projects.
- The applicant provides supporting documentation in Exhibits F.1(a) and F.1(b).

In Section E, pages 68-69, the applicant states that there will be no start-up costs or initial operating expenses because DUH currently provides MRI services.

**Availability of Funds**

In Section E, page 67, the applicant states that the capital cost will be funded by Duke University Health System, Inc. through accumulated reserves. Exhibit F.2 (a) contains a letter from the interim Chief Financial Officer stating their commitment to fund the project through DUHS’ accumulated cash reserve. In Exhibit F.2(b), the applicant provides the 2022 and 2023 consolidated balance sheets for DUHS, demonstrating sufficient cash and cash equivalents and assets to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibits F.2(a) and F.2(b) of the application.

**Financial Feasibility**

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

Duke University Hospital	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
	FY2026	FY2027	FY2028
Total Weighted Procedures*	66,676	68,014	69,445
Total Gross Revenues (Charges)	\$199,658,316	\$203,844,347	\$208,337,012
Total Net Revenue	\$52,559,810	\$54,145,627	\$55,836,727
Average Net Revenue per Procedure	\$788	\$796	\$804
Total Operating Expenses (Costs)	\$27,370,854	\$28,165,631	\$29,073,284
Average Operating Expense per Procedure	\$411	\$414	\$419
Net Income	\$25,188,956	\$25,979,996	\$26,763,443

\*DUH and Southpoint

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 124-128. 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. 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

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.
- (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 2023 SMFP need determination.

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

The following table identifies the existing and approved fixed MRI scanners located in the Durham County service area, summarized from Table 17E-1, page 340 of the 2023 SMFP:

Facility	Total # Fixed MRI Scanners	Total # of MRI Scans	Total # Adjusted of MRI Scans
Duke Regional Hospital	2	9,506	12,452
Duke University Hospital-Main	9	43,694	57,190
Duke University Hospital-Southpoint Clinic	1	1,827	1,916
Duke Imaging-Arringdon	1	1,048	1,113
Durham Diagnostic Imaging	1	1,684	1,824
EmergeOrtho-Southpoint	1	2,383	2,402
EmergeOrtho William Penn Plaza	1	4,607	4,694

Source: 2023 SMFP

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

*“As set forth above, DUHS MRI utilization at its existing facilities has increased significantly across the system in recent years, reflecting a growing demand for these services. This project is designed to address capacity constraints at DUH and ensure access for inpatient, outpatient, and emergency patients. As shown in Section C.4, DUHS demonstrates the need the population has for the proposed project based on demographic data specific to the service area, historical utilization, and qualitative benefits.”*

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:

- DUH is experiencing capacity constraints and high utilization of the existing fixed MRI scanners.
- The applicant demonstrates the need to expand MRI services based on demographic data and historical utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- There is a need determination in the 2023 SMFP for the proposed fixed MRI scanner in Durham County.
- The applicant adequately demonstrates that the proposed fixed MRI scanner is needed in addition to the existing or approved fixed MRI scanner.

### **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 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 2023 SMFP need determination.

In Section Q, Form H, page 12, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Duke University Hospital	Current Staff	Projected FTE Staff		
	as of 06/30/2023	1 <sup>st</sup> Full FY FY2026	2 <sup>nd</sup> Full FY FY2027	3 <sup>rd</sup> Full FY FY2028
MR Technologists	42.22	68.32	68.32	69.44
Registered Nurses	13.51	15.68	15.68	16.80
Radiology Supervisor	2.23	3.24	3.24	3.24
Assistant Nurse Manager	1.17	1.12	1.12	1.12
Clinical Tech Assistant	1.72	0.78	0.78	0.78
Orientees	1.89	0.00	0.00	0.00
Temp Agency	1.53	0.00	0.00	0.00
<b>TOTAL</b>	<b>64.27</b>	<b>89.14</b>	<b>89.14</b>	<b>91.38</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 77-78, 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:

- DUH is an established employer in the service area and recruits qualified staff through DUHS' Nurse Recruitment and Human Resources.
- DUH is active in the community and regularly interacts with clinical training programs in the service area.
- DUHS requires all clinical staff to complete appropriate orientation/training and maintain licensure and certification in their respective positions.

**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.



The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2023 SMFP need determination.

### **Ancillary and Support Services**

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On page 79, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because DUH currently provides MRI services and all required ancillary and support services are already in place.

### **Coordination**

In Section I, page 80, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- DUHS is an established healthcare system in the service area with existing relationships with local health care and social service providers.
- Duke physicians donate medical services to eligible uninsured patients through “*Project Access.*”

### **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. Therefore, Criterion (9) is not applicable to this review.

NA

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

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

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to acquire no more than one fixed MRI scanner pursuant to the 2023 SMFP need determination.

In Section K, page 84, the applicant states that the project involves renovating 1,080 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 84-85, 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 is proposing to upfit a space in an existing medical office building on the main campus.
- The applicant will work with project managers and architects to develop a cost-effective plan.
- Upfit costs are based on the costs of similar projects, construction costing data, and the architect's experience.

On page 85, 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 because charges and reimbursement are established by the payor sources. The applicant states that any costs incurred are necessary to provide critical screening and diagnostic services to patients.

On page 85, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit F.1(a).

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 87, the applicant provides the historical payor mix during FY2022 for the proposed services, as shown in the table below.

<b>Duke University Hospital Historical Payor Mix Last Full FY 07/01/2021-06/30/2022</b>	
<b>Payor Source</b>	<b>% of Total</b>
Self-Pay	1.7%
Charity Care	2.6%
Medicare*	38.6%
Medicaid*	11.5%
Insurance*	42.2%
Workers Compensation	0.2%
TRICARE	1.5%
Other	1.8%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

In Section L, page 88, the applicant provides the following comparison.

<b>Duke University Hospital</b>	<b>Percentage of Total Patients Served</b>	<b>Percentage of the Population of the Service Area (Durham and Caswell Counties)</b>
Female	58.91%	51.8%
Male	40.42%	NA
Unknown	0.67%	NA
64 and Younger	64.05%	84.6%
65 and Older	35.95%	15.4%
American Indian	0.67%	1.0%
Asian	3.50%	5.7%
Black or African-American	26.07%	35.0%
Native Hawaiian or Pacific Islander	0.15%	0.1%
White or Caucasian	61.14%	55.4%
Other Race	3.74%	2.8% (2 or more races)
Declined / Unavailable	4.74%	NA

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

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

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

- (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, pages 89-90, the applicant states:

*“DUHS has no specific obligation under federal regulations to provide uncompensated care for community service, or access by minorities and handicapped persons. However, DUHS does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. DUHS will continue to have a policy to provide all services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay or any other factor that would classify a patient as underserved. The proposed hospital services will be available to and accessible by any patient, including the medically underserved, having a clinical need for the offered services.”*

In Section L, page 90, 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

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 91, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Duke University Hospital Fixed MRI Scanners Projected Payor Mix 3<sup>rd</sup> Full FY, FY2028</b>	
<b>Payor Source</b>	<b>% of Total</b>
Self-Pay	0.65%
Charity Care	2.22%
Medicare*	34.73%
Medicaid*	11.15%
Insurance*	46.19%
Workers Compensation	0.20%
TRICARE	2.64%
Other	2.22%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.65% of total services will be provided to self-pay patients, 2.22% to charity care patients, 34.73% to Medicare patients and 11.15% to Medicaid patients.

On page 91, the applicant provides the assumptions and methodology used to project payor mix during the first three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on DUH's FY2023 (07/01/2022-6/30/2023) historical payor mix.
- The applicant accounts for a one-time payor source adjustment of 1.7 percent from insurance to Medicare and a one-time service line adjustment of 1.84 percent for inpatient procedures and 1.6 percent for outpatient procedures.

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 93, 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

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

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

C

In Section M, page 94, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on DUH's status as an Academic Medical Center Teaching Hospital serving medical students and professionals.

### **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 2023 SMFP need determination.

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

The following table identifies the existing and approved fixed MRI scanners located in the Durham County service area, summarized from Table 17E-1, page 340 of the 2023 SMFP:

Facility	Total # Fixed MRI Scanners	Total # of MRI Scans	Total # Adjusted of MRI Scans
Duke Regional Hospital	2	9,506	12,452
Duke University Hospital-Main	9	43,694	57,190
Duke University Hospital-Southpoint Clinic	1	1,827	1,916
Duke Imaging-Arringdon	1	1,048	1,113
Durham Diagnostic Imaging	1	1,684	1,824
EmergeOrtho-Southpoint	1	2,383	2,402
EmergeOrtho William Penn Plaza	1	4,607	4,694

Source: 2023 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 95, the applicant states:

*“This proposal will increase MRI scanning capacity at Duke University Hospital, which may decrease the wait times for scheduled procedures and reduce the time necessary to treat, admit, and/or discharge emergency department and inpatients. It will improve access to imaging necessary to coordinate a range of critical clinical services provided by the hospital. It will increase patients’ ability to choose their care based on their clinical needs, not just scheduling availability.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 95, 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,*



*increasing capacity could decrease inpatient length of stay for inpatients needing imaging prior to surgery, treatment, or discharge.”*

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 95, the applicant states:

*“...this project will directly increase access to MRI services, including for medically underserved patients...Decreasing wait times for procedures can reduce delays in treatment, benefitting quality of care across a range of services. DUH has a national reputation for quality and safety, and this project will have a positive impact on the quality of MRI services available in the service area.*

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, page 95, the applicant states:

*“...this project will directly increase access to MRI services, including for medically underserved patients as set forth in Section L.”*

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

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

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

## **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

In Section Q, Form O, page 13, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of four of these types of facilities located in North Carolina.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, DUHS is not aware of any deficiencies in quality of care. The applicant states that Wilson Medical Center had a finding of immediate jeopardy in 2022 but is currently in compliance. The applicant states that Wilson Medical Center is not operated by DUHS. 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, incidents related to quality of care had not occurred in any of these facilities. 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 four 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- According to Table 17E-1 of the 2023 SMFP, the applicant or related entity owns and operates 13 fixed MRI scanners in Durham County.

<b>Facility</b>	<b># of Fixed MRI Scanners</b>
Duke Regional Hospital	2
Duke University Hospital-Main	9
Duke University Hospital-Southpoint Clinic	1
Duke Imaging-Arrington	1
<b>Total</b>	<b>13</b>

(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- The applicant does not own or operate an approved fixed MRI scanner in Durham County.

(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- The applicant does not own or operate a mobile MRI scanner that provides mobile MRI services in Durham County.

(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- On September 27, 2023, the applicant was conditionally approved for one mobile MRI scanner in Durham County (Project ID# J-12378-23). However, at the time this application was submitted, the Agency had not issued a Certificate of Need.

(5) *provide projected utilization of the MRI scanners identified in Subparagraphs (1) through (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;*

In Section Q, pages 106-109, the applicant provides projected utilization.

<b>DUHS Fixed MRI Scanners Projected Utilization</b>			
	<b>1<sup>st</sup> Full FY FY2026</b>	<b>2<sup>nd</sup> Full FY FY2027</b>	<b>3<sup>rd</sup> Full FY FY20258</b>
<b>DUH &amp; Southpoint</b>			
# of Units	11	11	11
# of Procedures	50,885	51,933	53,060
# of Weighted Procedures	66,676	68,014	69,445
<b>Duke Regional Hospital</b>			
# of Units	2	2	2
# of Procedures	11,517	11,867	12,254
Weighted Procedures	14,713	15,099	15,526
<b>Duke Imaging Arrington</b>			
# of Units	2	2	2
# of Procedures	9,012	8,988	8,972
# of Weighted Procedures	9,576	9,551	9,534

<b>Duke Imaging Mobile MRI (Project ID# J-12378-23) Approved Mobile MRI Scanner Projected Utilization</b>				
	<b>Partial FY FY2025</b>	<b>1<sup>st</sup> Full FY FY2026</b>	<b>2<sup>nd</sup> Full FY FY2027</b>	<b>3<sup>rd</sup> Full FY FY20258</b>
# of Units	1	1	1	1
# of Procedures	1,625	3,423	3,809	4,058
# of Weighted Procedures	1,770	3,729	4,149	4,421

(6) *provide the assumptions and methodology used to project the utilization required by Subparagraph (5) of this Paragraph;*

-C- In Section Q, pages 110-120, the applicant provides the assumptions and methodology used to project utilization for the existing and proposed fixed MRI scanners during each of the first three full fiscal years of operation following completion of this project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(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 fixed 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 fixed 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*

<b>DUHS Total # of Adjusted MRI Procedures</b>	<b>Total # of Fixed MRI Scanners</b>	<b>Total # of Adjusted MRI Procedures per Fixed MRI Scanner</b>
94,505	15	6,300

- (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 project.*

<b>Duke Imaging Mobile MRI (Project ID# J-12378-23)</b>				
<b>Approved Mobile MRI Scanner</b>				
<b>Projected Utilization</b>				
	<b>Partial FY FY2025</b>	<b>1<sup>st</sup> Full FY FY2026</b>	<b>2<sup>nd</sup> Full FY FY2027</b>	<b>3<sup>rd</sup> Full FY FY20258</b>
# of Units	1	1	1	1
# of Procedures	1,625	3,423	3,809	4,058
# of Weighted Procedures	1,770	3,729	4,149	4,421

- (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 (1) and (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 (3) and (4) of this Paragraph 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 fixed 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 fixed 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 fixed MRI scanners in the fixed MRI scanner service area.*
- NA- 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.