

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 3, 2025

Findings Date: March 3, 2025

Project Analyst: Ena Lightbourne

Co-Signer: Mike McKillip

COMPETITIVE REVIEW

Project ID #: J-12576-24
Facility: UNC Durham County Imaging
FID #: 240872
County: Durham
Applicant: UNC DCI, LLC
Project: Acquire no more than one fixed MRI scanner pursuant to the 2024 SMFP need determination

Project ID #: J-12577-24
Facility: Duke Imaging Arrington
FID #: 190274
County: Durham
Applicant: Duke University Health System, Inc.
Project: Acquire no more than one additional fixed MRI scanner pursuant to the 2024 SMFP need determination for a total of no more than 3 fixed MRI scanners upon project completion

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

REVIEW CRITERIA

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

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

C-Both Applications

Need Determination

The 2024 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for an additional fixed MRI scanner in North Carolina by service area. Application of the need methodology in the 2024 SMFP identified a need for one fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one fixed MRI scanner, for a total of two fixed MRI scanners. However, pursuant to the need determination, only one fixed MRI scanner may be approved in this review.

Policies

There are two policies in Chapter 4 of the 2024 SMFP is applicable to both applications: *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.”

Policy GEN-4 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."

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

UNC DCI, LLC., hereinafter referred to as "the applicant" or UNC DCI, proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP, to be located at a new freestanding diagnostic center, UNC Durham County Imaging, in the city of Durham.

Need Determination. The applicant does not propose to acquire more fixed MRI scanners that are determined to be needed in the Durham/Caswell/Warren multicounty fixed MRI scanner service area.

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

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 31-32, the applicant describes the project's plan to assure improved energy efficiency and water conservation. The applicant states that the design will incorporate materials and equipment that minimize utilities consumptions and energy costs, in compliance with all applicable federal, state and local building codes and requirements for energy efficiency and consumption.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response 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 acquire 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 that the application is consistent with *Policy GEN-4* and includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

Duke University Health System, Inc., hereinafter referred to as “the applicant”, or “DUHS”, proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP, for a total of three fixed MRI scanners at the existing diagnostic center, Duke Imaging Arrington (“Arrington”), in Morrisville.

Need Determination. The applicant does not propose to acquire more fixed MRI scanners that are determined to be needed in the Durham/Caswell/Warren multicounty fixed MRI scanner service area.

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

Policy GEN-4. The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 29-30, the applicant describes the project's plan to assure improved energy efficiency and water conservation. The applicant states that 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.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Response 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 acquire 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 that the application is consistent with *Policy GEN-4* and includes a written statement describing the project's plan to assure improved 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.

C-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

Patient Origin

On page 335, the 2024 SMFP defines the fixed MRI service area as "... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*" Therefore, for the purpose of this review, the fixed MRI scanner service area is a multicounty service area: Durham, Caswell, and Warren counties. Facilities may also serve residents of counties not included in their service area.

In Section C, page 38, the applicant states that the proposed facility is not an existing facility. There is no historical patient origin to report. The following table illustrates projected patient origin.

UNC Durham County Imaging MRI Services Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	07/01/2027- 06/30/2028		07/01/2028- 06/30/2029		07/01/2029- 06/30/2030	
	FY 2028		FY 2029		FY 2030	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Durham	1,108	60.0%	1,546	60.0%	2,067	60.0%
Wake	358	19.4%	500	19.4%	668	19.4%
Orange	187	10.1%	260	10.1%	348	10.1%
Chatham	102	5.5%	142	5.5%	189	5.5%
Other^	92	5.0%	129	5.0%	173	5.0%
Total	1,847	100.0%	2,577	100.0%	3,445	100.0%

Source: Section C, page 39

^ Alamance, Caswell, Cumberland, Franklin, Granville, Guilford, Halifax, Harnett, Johnston, Mecklenburg, Person, and potentially other NC counties and other states.

In Section C, page 39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on the patient origin of other fixed freestanding MRI providers in the service area and the applicant’s assumptions and methodology to project utilization of MRI services, stated in Section Q, pages 121-127. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Analysis of Need

In Section C, pages 42-57, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- There is a need in the 2024 SMFP for one fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area. (page 42)
- The historical population growth. Durham County has seen significant population growth in the last ten years and is projected to see a growth of 20,000 residents in the next five years, according to data from the North Carolina Office of State Budget Management (NCOSBM). (pages 43-44)
- The applicant states that there are other factors to support the need for the proposed services such as demographics, particularly age and race. According to NCOSBM data, the 65+ age group in Durham County has experienced a Compound Annual Growth Rate (CAGR) rate of 4.1 percent in the last ten years, higher than the statewide growth for this group during the same period. This group’s population is projected to grow by 6,477 residents by 2029. This is significant because of their higher utilization rates of healthcare services and the need for early detection of diseases such as dementia and

Alzheimer's. Moreover, African Americans make up 33.7 percent of the Durham County population, the second highest group. This group is more likely to be negatively impacted by diseases such as diabetes, heart disease, and cancer due to the lack of sufficient medical treatment. The data cited by the applicant shows that this may be due to the group's limited access to healthcare services because of the physical distance, lack of insurance, and/or documented healthcare racism. (pages 45-50)

- The applicant states that there is a need to continue to expand MRI capacity in Durham County due to the incidence of cancer cases and deaths in the county, particularly during 2018-2022. The applicant states that the proposed 3.0T MRI scanner will have the capabilities to accurately identify breast and prostate cancerous tumors early to allow for timely treatment and subsequently enhance outcomes. (pages 50-51)
- The applicant is proposing to locate the freestanding diagnostic center in the southern part of Durham County. The applicant concluded that there is need for freestanding fixed MRI capacity in that area based on the historical and projected population growth in the south region. The South Durham County population (per fixed MRI scanner) is projected to experience the highest growth. Also, the applicant's proposed location will enhance access to freestanding MRI services as most MRI providers are located in the central/west region. There are two existing freestanding centers in south Durham County that are located more geographically distant from each other in comparison to the denser distribution of MRI providers in north Durham County. Moreover, the proposed freestanding diagnostic center will serve as a convenient and cost-saving alternative for south Durham MRI patients. (pages 51-57)

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

- The 2024 SMFP identifies the need for one additional fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area.
- The applicant provides information and data to support its assertions regarding service area population growth and aging, disease risk factors and the need to enhance access and expand capacity in the southern part of the Durham County.

Projected Utilization

In Section Q, page 119, the applicant provides projected utilization, as illustrated in the following table.

UNC Durham County Imaging				
	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	11/1/2026-6/30/2027	FY 2028	FY 2029	FY 2030
# of Units	1	1	1	1
# of Procedures	913	2,032	2,835	3,789
# of Adjusted Procedures	996	2,216	3,092	4,134

In Section Q, pages 121-127, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant begins its projections with identifying the historical utilization of Durham County residents who receive MRI services from providers in and outside of Durham County. This group experienced a CAGR of 4.8 percent during FFY 2019 through FFY 2023. An average of 79.0 percent were Durham County residents who were served by a Durham County provider. See *Table 1* below.

	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023	CAGR
Patients from Durham County	17,616	17,318	18,720	18,652	21,262	4.8%
Percentage of Durham County Residents Served in Durham County	80.1%	79.4%	79.8%	79.2%	78.0%	

Source: Section C, page 122; NCDHSR Patient Origin Reports

Based on the service area projected population growth and aging, as stated in the applicant’s Demonstration of Need, the applicant projects the number of MRI patients originating from Durham County regardless of treatment location by applying the historical growth rate of 4.8 percent. The applicant projects that 78.0 percent will be patients originating from Durham County and served in Durham County which is consistent with the FFY 2023 percentage.

	FFY 2023	FFY 2024	FFY 2025	FFY 2026	FFY 2027	FFY 2028	FFY 2029	FFY 2030	CAGR
Patients from Durham County	21,262	22,286	23,359	24,484	25,663	26,898	28,194	29,551	4.8%
In-County Patients (%)	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%	78.0%	
Patients from Durham County Served in Durham County	16,584	17,383	18,220	19,097	20,017	20,981	21,991	23,050	

Source: Section C, page 122; NCDHSR Patient Origin Reports

The following table illustrates the incremental growth of patients originating from Durham County and remained in Durham County for services, using the percentage of growth illustrated in *Table 2* above. The applicant states that these patients do not currently contribute to patient volumes or market share at any existing MRI provider in the county but represent an available MRI market share.

Table 3: Incremental Growth of Patients from Durham County Served Durham County								
	FFY 2023	FFY 2024	FFY 2025	FFY 2026	FFY 2027	FFY 2028	FFY 2029	FFY 2030
Patients from Durham County Served in Durham County (78.0%)	16,584	17,383	18,220	19,097	20,017	20,981	21,991	23,050
New Durham County Patients from FFY 2023	0	799	1,636	2,513	3,432	4,396	5,407	6,465

Source: Section C, page 123

The applicant converts the projected number of new Durham County patients illustrated in *Table 3* above, to comply with the state fiscal year using the following formula: *Current SFY Procedures = (Current FFY Procedures x 0.75 + Prior FFY Procedures x 0.25)*.

Table 4: New Durham County Patients Converted to UNC DCI Fiscal Year							
	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028 (PY1)	SFY 2029 (PY2)	SFY 2030 (PY3)
New Durham County Patients from FFY 2023	599	1,426	2,294	3,203	4,155	5,154	6,201

Source: Section C, page 123

The applicant projects that one-third of the new Durham County patients will be served by the proposed facility. The applicant states that projections are reasonable and based on factors such as convenience, affordability, services offered, and UNC Health’s (parent entity and sole member of UNC DCI, LLC) reputation for quality care. The applicant states that projections are further supported by the projected population growth in the south region of Durham County, which is almost half of the projected population growth of the entire county. The applicant projects that the proposed facility will serve 2,067 Durham County patients in the third project year ($6,201 \times 0.333 = 2,067$). See *Table 5* below.

Table 5: Potential Durham County Patients Served at Proposed Facility, Before Ramp-Up							
	SFY 2024	SFY 2025	SFY 2026	SFY 2027	SFY 2028 (PY1)	SFY 2029 (PY2)	SFY 2030 (PY3)
New Durham County Patients from FFY 2023	599	1,426	2,294	3,203	4,155	5,154	6,201
Potential Durham County Patients Served (33.3%)	0	0	0	712	1,385	1,718	2,067

Source: Section C, page 124

Note: The proposed UNC Durham County Imaging facility will begin service on November 1, 2026. As such, FY 2027 is a partial year representing eight months of operation.

The applicant assumes that the proposed facility will also serve patients originating from outside the county. To project utilization for this group, the applicant examined the historical utilization (FFY 2023) of patients originating from outside of Durham County and served by the four existing freestanding fixed MRI centers located throughout the north and south region of Durham County. The following table illustrates the in-migration rates for two facilities located in the south region of Durham County and two facilities located in the north region of the county. The applicant states that the two facilities located in the south region, EmergeOrtho-South point and Duke Imaging Arringdon, experienced high in-migration rates primarily due to their location on the southeastern and southwestern border of the county.

Existing Freestanding MRI Facilities	Total Patients Served	Durham County Residents	In-migration %
Durham-Independence Park (Dark Diagnostic Imaging) (<i>North Region</i>)	2,330	1,022	56.1%
EmergeOrtho-William Penn Plaza (EmergeOrtho) (<i>North Region</i>)	3,749	1,369	63.5%
EmergeOrtho-Southpoint (EmergeOrtho) (<i>South Region</i>)	2,748	759	72.4%
Duke Imaging Arringdon (Duke University Health System) (<i>South Region</i>)	2,722	690	74.7%

Source: Section Q, page 124; NCDHSR Patient Origin Reports, FFY 2023

Based on the in-migration rates experienced by the other facilities, the applicant projects a conservative in-migration rate of 40 percent for the proposed facility. See *Table 7* below.

	SFY 2027	SFY 2028 (PY1)	SFY 2029 (PY2)	SFY 2030 (PY3)	In-migration
Potential Durham County Patients Served (33%)	712	1,385	1,718	2,067	
Immigration	474	923	1,145	1,378	40.0%
Total Potential Patients Served	1,186	2,309	2,863	3,445	

Source: Section Q, page 125

The applicant projects an initial ramp-up period for the first three project years, based on UNC DCI's efforts for community outreach and building a provider referral base.

	SFY 2027	SFY 2028 (PY1)	SFY 2029 (PY2)	SFY 2030 (PY3)
Total Potential Patients Served	1,186	2,309	2,863	3,445
Ramp Up Period	70.0%	80.0%	90.0%	100.0%
Total Patients Served	830	1,847	2,577	3,445

Source: Section Q, page 125

To demonstrate that the proposed fixed MRI scanner will meet the performance standard for fixed MRI scanners, the applicant used FFY 2023 patient origin data and the proposed 2025 SMFP MRI procedure data, to identify the Durham County FFY 2023 ratio of freestanding fixed MRI patients to unadjusted outpatient fixed MRI procedures and the ratio of freestanding fixed MRI patients to the total adjusted outpatient procedures. The applicant noted that the patients identified were not differentiated by county of origin and only data for unadjusted *base* outpatient and unadjusted *complex* outpatient fixed MRI procedures were included.

	FFY 2023
Total MRI Patients Served at Freestanding Fixed Durham County Facilities*	11,549
Unadjusted Base Outpatient Fixed MRI Procedures [^]	10,330
Unadjusted Complex Outpatient Fixed MRI Procedures [^]	2,688
Total Unadjusted Outpatient Fixed MRI Procedures	13,018
Total Adjusted Outpatient Fixed MRI Procedures	13,588
Ratio of "Freestanding Fixed MRI Patients" to "Total Unadjusted Outpatient Fixed MRI Procedures"	1.1
Ratio of "Freestanding Fixed MRI Patients" to "Total Adjusted Outpatient Procedures"	1.2

Source: Section Q, page 126

*NCDHSR Patient Origin Reports, FFY 2023

[^]Proposed 2025 SMFP, Table 15E-1, page 343

To project the total number of unadjusted and adjusted MRI procedures performed during the first three project years, the applicant applied the ratio of unadjusted and adjusted procedures illustrated in the table above. The applicant projects the UNC Durham County Imaging will perform 4,134 adjusted MRI procedures in the third project year.

	SFY 2027	SFY 2028 (PY1)	SFY 2029 (PY2)	SFY 2030 (PY3)
Total Patients Served	830	1,847	2,577	3,445
MRI Unadjusted Procedures (1:1.1 Ratio)	913	2,032	2,835	3,789
MRI Adjusted Procedures (1:1.2 Ratio)	996	2,216	3,092	4,134

Source: Section Q, page 126

As shown in the table above, the applicant’s projected utilization for the proposed fixed MRI scanner exceeds the performance standard promulgated in 10A NCAC 14C .2703 of 3,494 adjusted MRI procedures per fixed MRI scanner.

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

- The applicant provides reasonable and adequately supported data and uses reasonable methodologies and assumptions to identify the Durham County patient population to be served.
- The applicant’s projections are based on population projections for the proposed service area from the NCOSBM, historical MRI scanner utilization for the identified patient population from FFY 2019 to FFY 2023, the historical data of in-migration rates, and the ratio of adjusted and unadjusted MRI procedures of the existing MRI providers in Durham County.

Access to Medically Underserved Groups

In Section C, page 64, the applicant states:

“...UNC Health strives to provide adequate financial assistance and expand its overall capacity in order to meet the healthcare needs of all North Carolinians. UNC Health has a long and proud history of serving patients who require care, regardless of their ability to pay. UNC Health, the sole owner of UNC DCI, will ensure that patients with limited financial resources have access to the proposed fixed MRI services upon completion of the proposed project.”

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

Medically Underserved Groups	Estimated % of Total Patients in 3rd Full FY
Low-income persons	Not Tracked
Racial and ethnic minorities	43.8%
Women	63.8%
Persons with disabilities	Not Tracked
Persons 65 and older	30.4%
Medicare beneficiaries	32.2%
Medicaid recipients	12.3%

Source: Section C, page 65; FY 2024 Durham residents receiving outpatient MRI services at UNC facilities in Orange County.

In Section C, page 65, the applicant states that UNC Health does not have a method to track data that includes low-income persons and people with disabilities. However, these groups are not denied access to the proposed services. The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

Patient Origin

On page 335, the 2024 SMFP defines the fixed MRI service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Therefore, for the purpose of this review, the fixed MRI scanner service area is a multicounty service area: Durham, Caswell, and Warren counties. Facilities may also serve residents of counties not included in their service area.

Duke Imaging Arrington is an existing facility operating two fixed MRI scanners in Durham County. In Section C, pages 32-36, the applicant provides the facility’s historical (FY 2024) MRI patient origin. On pages 41-44, the applicant provides the projected patient origin for MRI services through the first three full fiscal years of operation (FY 2027 – FY 2029).

In Section C, page 40, and in Section Q, pages 116-126, the applicant provides the assumptions and methodology used to project patient origin. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s historical patient origin for its existing fixed MRI scanners located at Duke Imaging Arrington.

Analysis of Need

In Section C, pages 49-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- There is a need in the 2024 SMFP for one fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area. (pages 49-50)
- Historical population growth in the service area counties and the growth in the statewide historical MRI use rate has led to high utilization, which has resulted in capacity constraints for some hospital-based MRI scanners. (page 51)

- Growth in utilization of DUHS' existing MRI scanners located in Durham County, including the growth of outpatient procedures that grew significantly higher than inpatient procedures. (pages 52-53)
- DUHS has a broad physician referral network across several medical disciplines that has continued to expand, including the number of MRI referring providers for Duke Imaging Arrington. The applicant states that DUHS continues to engage in recruitment of specialty providers in the service area to meet the needs of the growing patient population. (pages 53-54)
- The benefits of expanding MRI capacity at the Arrington location include MRI services offered at a lower cost, the use of state-of-the art technology for high quality imaging and faster scan time, co-location of primary and specialty care providers, and accessibility due to the convenient location.

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

- The 2024 SMFP identifies the need for one additional fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area.
- The applicant provides reasonable and adequately supported historical growth data to support the need to expand MRI services at Duke Imaging Arrington and the service area.

Projected Utilization

In Section Q, pages 109-115, the applicant provides interim and projected utilization, as illustrated in the following tables.

Duke Regional Hospital: Fixed MRI Scanners						
	Last Full FY	Interim Full FY	Interim Full FY	1st Full FY	2nd Full FY	3rd Full FY
	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
# of Units	2	2	2	2	2	2
# of Procedures	11,224	11,769	12,285	12,511	13,167	13,877
# of Adjusted Procedures	14,769	15,448	16,098	16,426	17,236	18,109
DUHS Mobile MRI Scanner						
		Interim Full FY	Interim Full FY	1st Full FY	2nd Full FY	3rd Full FY
		FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
# of Units		1	1	1	1	1
# of Procedures		1,625	3,423	3,809	4,058	4,058
# of Adjusted Procedures		1,770	3,729	4,149	4,421	4,421
Duke University Hospital: Fixed MRI Scanners Main and Southpoint						
	Last Full FY	Interim Full FY	Interim Full FY	1st Full FY	2nd Full FY	3rd Full FY
	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
# of Units	10	10	10	11	11	11
# of Procedures	47,164	52,399	54,802	55,822	58,782	61,982
# of Adjusted Procedures	65,908	69,041	72,071	73,545	77,226	81,187
Duke Imaging Arrington: Fixed MRI Scanners						
	Last Full FY	Interim Full FY	Interim Full FY	1st Full FY	2nd Full FY	3rd Full FY
	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
# of Units	2	2	2	3	3	3
# of Procedures	5,976	6,308	6,609	9,080	9,374	9,926
# of Adjusted Procedures	6,643	6,822	7,147	9,820	10,138	10,735

In Section Q, pages 116-126, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant identifies the historical utilization, including growth rates, of DUHS's existing fixed MRI scanners in Durham County.

DUHS Durham MRI Utilization-Historical Unadjusted Procedures								
DUHS Durham County MRI Service Locations	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	5-Year CAGR 19-24	3-Year CAGR
Duke Regional Hospital Fixed Inpatient	2,359	2,222	2,504	2,237	2,417	2,723		
Duke Regional Hospital Fixed Outpatient	6,812	6,092	6,844	7,756	8,150	8,501		
Duke Regional Hospital Mobile Inpatient	1	5	8	4	2	7		
Duke Regional Hospital Mobile Outpatient	2,577	2,384	2,746	3,270	3,544	3,690		
Duke University Hospital Fixed Inpatient	9,254	8,812	8,986	9,478	9,973	10,853		
Duke University Hospital Fixed Outpatient	33,868	34,092	37,160	37,423	37,971	39,043		
DUH Southpoint (included in DUH total above)	1,830	1,471	1,827	1,860	1,963	1,835		
DUH Lenox Baker Before Relocation (Included in DUH total above)	683							
DUH Page Road Before Relocation (Included in DUH total above)	1,022	674	625	6				
Duke Imaging Arringdon			258	3,745	4,193	5,976		
Annual growth at Arringdon				1476%	13%	42.5%		
Total DUHS Durham Inpatient MRI	11,614	11,039	11,498	11,719	12,392	13,583	3.2%	5.7%
Total DUHS Durham Outpatient MRI	43,257	42,568	47,008	52,194	53,858	57,210	5.75%	6.8%

Source: Section Q, page 117

As illustrated above, DUHS Durham inpatient MRI utilization experienced a CAGR of 5.7 percent during 2021-2024. Outpatient MRI utilization had an annual growth of 6.8 percent. The applicant projects that outpatient MRI volumes at Durham County sites prior to any location shift will increase by the 2019-2024 5-year CAGR of 5.75 percent. The applicant states that projections are reasonable considering the historical growth trends. The following table illustrates projections using the 5-year CAGR.

Projected Outpatient MRI Volume at Durham County Sites Prior to Any Location Shift					
	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
DUHS Durham Sites Outpatient MRI	60,500	63,979	67,658	71,549	75,664

Source: Section Q, page 118

Utilization of MRI Scanners at Duke Imaging Arringdon (pages 118-120)

Step 1: The applicant projects utilization at Arrington using the 5-year outpatient CAGR of 5.75 percent of all DUHS locations, as stated above. The applicant states that projections are conservative considering historical growth trends, including Arrington's historical growth of its existing MRI scanners.

Step 2: The applicant projects that in FY 2027, the proposed MRI scanner will have a one-time increase equal to 3.1 percent of the total projected DUHS Durham County sites outpatient MRI volumes. The applicant's projections are based on the anticipated shift of volume as MRI capacity increases at Arrington. The applicant states that with the annual growth rate and the one-time increase of 3.1 percent, the increase would be lower than the historical growth rate during implementation of the two other existing MRI scanners at Arrington.

Step 3: To project volumes for FY 2027, the applicant accounts for the anticipated shifts of MRI volumes from Arrington to other DUHS sites projected in previous CON applications for a mobile MRI scanner in Durham County (J-12378-23) and a fixed MRI scanner in Wake County (J-12395-23).

Step 4: To project FY 2028 and FY 2029, the applicant applies the annual growth rate of 5.9 [5.75] percent in outpatient volumes resulting from the FY 2027 projected utilization, calculated in *Steps 1-3*.

Step 5: For FY 2028 and FY 2029, the applicant accounts for the anticipated shifts of volume from Arrington to other DUHS sites projected in previous CON applications, J-12378-23 and J-12395-23.

Step 6: The applicant assumes that MRI volumes will be spread equally across all three existing and proposed MRI scanners at Arrington. The following table illustrates projected unweighted MRI volumes at Arrington applying *Steps 1* through *6*.

Projected Arrington MRI Volumes-Unadjusted					
Unweighted MRI Volumes	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Arrington Volumes FY 2025-2027 Pre-Shift (5.75% Annual Growth Rate) (1)	6,320	6,683	7,067		
FY 2027 shift from Duke University Hospital and Duke Regional Hospital for new machine = 3.0% (2)			2,109		
Projected shift from Arrington to DUHS mobile sites (3)	(12)	(33)	(40)		
Projected shift from Arrington to Garner MRI (3)		(41)	(56)		
Total Arrington Volumes FY 2025-FY 2027 (unadjusted)	6,308	6,609	9,080		
Arrington Volumes FY 2028-2029 Pre-Shift (5.75% Annual Growth Rate) (4)				9,602	10,154
Projected shift from Arrington to DUHS mobile sites (5)				(43)	(43)
Projected shift from Arrington to Garner MRI (5)				(71)	(71)
Total Arrington Volumes FY 2028-FY 2029 (unadjusted, 3 scanners)				9,374	9,926

Source: Section Q, page 119

The applicant projects adjusted MRI volumes for FY 2024 based on procedure complexity using the weighting adjustment methodology demonstrated in the 2024 SMFP, as illustrated in the tables below.

MRI Adjustment Calculation-Arrington MRI 2024		
Category	Total Unadjusted	Total Adjusted
Simple	3,680	3,680
Complex	2,296	2,783
Total	5,976	6,463
Ratio Adjusted/Unadjusted		1.08

Source: Section Q, page 119

The applicant applies the adjustment factor to project volumes.

Projected Adjusted MRI Volumes-Arrington MRI					
	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Arrington Volume (Unadjusted)	6,308	6,609	9,080	9,374	9,926
Arrington Volume (adjusted)	6,822	7,148	9,820	10,138	10,735
Number of Scanners	2	2	3	3	3
Adjusted Procedures/Machine	3,411	3,574	3,273	3,379	3,578

Source: Section Q, pages 119-120

As shown in the table above, the applicant's projected utilization for the proposed fixed MRI scanner exceeds the performance standard promulgated in 10A NCAC 14C .2703 of 3,494 adjusted MRI procedure per fixed MRI scanner.

In Section Q, page 120, the applicant states that projected utilization is reasonable based on factors such as Arrington serving as a non-hospital-based alternative, the facility's quick ramp-up periods during the implementation of the first two fixed MRI scanners, historical growth in DUHS outpatient MRI volumes, and its convenient geographical location and broad range of MRI services offered.

Utilization of Other DUHS Fixed Scanners in the Service Area (pages 121-124)

Step 1-2: The applicant identifies the existing DUHS fixed scanners operating in the service area. Duke University Hospital has ten existing and one approved fixed scanner at all hospital locations, including Southpoint. The applicant states that the approved fixed scanner will begin operation in FY 2026. Duke Regional Hospital operates two fixed MRI scanners.

Step 3: The applicant projects that inpatient and outpatient volumes of the eleven fixed MRI scanners will grow at the DUHS' Durham County MRI historical 5-year CAGR rate.

Step 4: Of the projected one-time shift of volume to Arrington in FY 2027, the applicant projects that 377 will come from Duke Regional Hospital and 1,732 will come from Duke University Hospital. The applicant projects the same reduction in volume for FY 2028 and FY 2029.

Step 5: The applicant accounts for the anticipated shifts of MRI volumes projected in previous CON applications; a mobile MRI scanner in Durham County (J-12378-23) and a fixed MRI scanner in Wake County (J-12395-23).

Step 6: To project total adjusted procedures, the applicant applies the average weighting for inpatient and outpatient procedures for each facility based on the FY 2024 average adjustments. The following tables illustrate the applicant's projected MRI volumes, projected shift volumes, and the adjustment assumptions.

Duke University Hospital and Duke Regional Hospital Projected Fixed MRI Volumes (FY 2019-FY 2024)						
DUHS Durham County Hospital Fixed MRI Volumes	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024
Duke University IP	9,254	8,812	8,986	9,478	9,973	10,853
Duke University OP (including Southpoint)	33,868	34,092	37,160	37,423	37,971	39,043
Less Adjustment for Shifts						
DUH OP after Shifts						
Total Duke University Hospital Unadjusted						47,164
Total DUH Adjusted Procedures						65,908
Duke Regional Hospital IP Fixed	2,359	2,222	2,504	2,237	2,417	2,723
Duke Regional Hospital OP Fixed	6,812	6,092	6,844	7,756	8,150	8,501
Less Adjustment for Shifts						
DRH OP Fixed After Shifts						
Total Duke Regional Hospital Fixed Unadjusted						11,224
Total DRH Fixed Adjusted Procedures						14,769

Source: Section Q, page 122

Duke University Hospital and Duke Regional Hospital Projected Fixed MRI Volumes (FY 2025-FY 2029)					
DUHS Durham County Hospital Fixed MRI Volumes	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Duke University IP	11,198	11,555	11,922	12,302	12,693
Duke University OP (including Southpoint)	41,288	43,663	46,173	48,829	51,637
Less Adjustment for Shifts	88	415	2,274	2,348	2,348
DUH OP after Shifts	41,200	43,248	43,899	46,481	49,289
Total Duke University Hospital Unadjusted	52,399	54,802	55,822	58,782	61,982
Total DUH Adjusted Procedures	69,041	72,071	73,545	77,226	81,187
Duke Regional Hospital IP Fixed	2,810	2,899	2,991	3,086	3,185
Duke Regional Hospital OP Fixed	8,990	9,507	10,054	10,632	11,243
Less Adjustment for Shifts	31	121	534	551	551
DRH OP Fixed After Shifts	8,959	9,386	9,520	10,081	10,692
Total Duke Regional Hospital Fixed Unadjusted	11,769	12,285	12,511	13,167	13,877
Total DRH Fixed Adjusted Procedures	15,448	16,098	16,426	17,236	18,109

Source: Section Q, page 122

Projected Shifts from DUHS Hospitals to Other Sites	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Duke University Hospital Campus to Mebane Mobile Site	60	164	210	215	215
Duke University Hospital Campus to Knightdale Mobile Site	21	52	62	63	63
Southpoint to Mebane Mobile Site	7	20	27	28	28
Duke University Hospital Total Shift to Mobile Sites	88	236	299	306	306
Duke University Hospital Campus to Garner Fixed		173	235	300	300
Southpoint to Garner Fixed		6	8	10	10
Total to Garner Fixed		179	243	310	310
Duke University Hospital Total Shift to Arringdon in 2027			1,732	1,732	1,732
Total Duke University Hospital Shift to Other Sites	88	415	2,274	2,348	2,348
Duke Regional Hospital Fixed to Mebane Mobile Site	29	81	104	108	108
Duke Regional Hospital Fixed to Knightdale Mobile Site	2	6	7	7	7
Duke Regional Hospital Total Shift to Mobile Site	31	87	111	115	115
Duke Regional Hospital Fixed to Garner Fixed		34	46	59	59
Duke Regional Hospital Total Shift to Arringdon			377	377	377
Total Duke Regional Hospital Fixed Shift to Other Sites	31	121	534	551	551

Source: Section Q, page 123

Duke Regional Hospital	FY 2024	
	Inpatient	Outpatient
No Contrast	1,622	3,866
Contrast/Complex	1,101	4,635
Total Unadjusted	2,723	8,501
Total Adjusted	5,285	9,484
Average Adjustment	1.94	1.12

Source: Section Q, page 124

Duke University Hospital	FY 2024	
	Inpatient	Outpatient
No Contrast	4,314	14,759
Contrast/Complex	6,539	24,284
Total Unadjusted	10,853	39,043
Total Adjusted	21,714	44,194
Average Adjustment	2.00	1.13

Source: Section Q, page 124

DUHS Orange County Fixed MRI Scanner (page 125)

DUHS replaced an existing grandfathered MRI scanner at Duke University Hospital and relocated the unit to Duke Imaging Coley Hall in Orange County. Duke University Hospital developed an MRI scanner under Policy AC-3 of the 2024 SMFP that went into service calendar 2024. The applicant states that the Orange County MRI scanner will not have a negative impact on DUHS meeting the MRI performance standard for Durham County due to the potential volume shift from DUHS sites in the county. The following table illustrates the projected number of average adjusted procedure per unit for the first three years of the project among all units (existing, approved, and proposed), including the Orange County MRI scanner.

Duke University Health System-Durham Conty Scanners + Orange County			
	FY 2027	FY 2028	FY 2029
# of Durham Co. Fixed MRI*	17	17	17
Orange Co. Fixed MRI	1	1	1
# of Adjusted Procedures-Durham Fixed MRI Sites (DUH, DRH, Arrington)	99,791	104,600	110,032
Average Adjusted Procedures per Unit	5,870	6,153	6,472

Source: Section Q, page 125

*Existing, Approved and Proposed

The following table illustrates the projected average adjusted procedures per unit for the first three years of the project, assuming that the Orange County scanner was 100 percent utilized, entirely comprised of a shift of volume away from DUHS Durham County MRI scanners without incremental growth.

Duke University Health System-Durham Conty Scanners + Orange County			
	FY 2027	FY 2028	FY 2029
# of Units	16	16	16
# of Adjusted Procedures	99,791	104,600	110,032
# of Projected Adjusted Procedures-6,240 (capacity of Orange County)	93,551	98,360	103,792
Average Adjusted Procedures per Unit	5,847	6,148	6,487

Source: Section Q, page 125

DUHS Mobile Scanner (page 126)

The following table illustrates the applicant’s projected utilization for the approved mobile MRI scanner (Project ID# J-12378-23). The scanner began services in June 2024. The applicant’s assumptions and methodology are outlined in the previously approved application. The applicant assumes that utilization will remain constant in the third project year.

DUHS Mobile MRI Procedures						
Days per Week	Host Site	FY 2025 MRI Procedures	FY 2026 MRI Procedures	FY 2027 MRI Procedures	FY 2028 MRI Procedures	FY 2029 MRI Procedures
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 Regional Hospital	368	757	781	809	809
Total (Unadjusted) MRI Scans		1,625	3,426	3,809	4,058	4,058

Source: Section Q, page 126

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

- The applicant relied on the historical utilization and growth trends of DUHS existing MRI scanners in Durham County to project utilization.
- The applicant provides reasonable methodologies and assumptions to project volume shifts and ramp-up periods.

Access to Medically Underserved Groups

In Section C, page 59, the applicant states:

“All individuals including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will continue to have access to DUHS’s MRI

services, as clinically appropriate. DUHS does not and will not discriminate based on race, ethnicity, age, gender, disability, or sexual orientation.”

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

Medically Underserved Groups	Estimated % of Total Patients in 3 rd Full FY
Low-income persons	9.6%*
Racial and ethnic minorities	9.1%
Women	58.7%
Persons with disabilities	N/A
Persons 65 and older	47.0%
Medicare beneficiaries	46.3%
Medicaid recipients	14.1%

Source: Section C, pages 60-61

*Calculated as patients with Medicaid and/or charity or reduced care discounts.

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 information provided in Section C, pages 59-61, and Exhibits C.11 and L.4.

Conclusion

The Agency reviewed the:

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

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

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

NA-Both Applications

Neither of the applicants proposes to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section E, pages 78-79, 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:

Develop the Proposed MRI at Another Location-The applicant states that developing the proposed fixed MRI scanner in another location was considered, however, the proposed site proved to be the most effective alternative. The applicant states that the proposed site would be geographically accessible to residents of Caswell and Warren counties. Moreover, the proposed site will be in proximity to the previously approved UNC Hospitals-RTP which would enhance the cost-effectiveness and efficiency of the project and simplify coordination of care.

Construct a New Freestanding Diagnostic Facility-The applicant states that leasing and upfitting an existing space would be more cost-effective than developing a new facility. It would avoid the costs associated with developing a new construction. The applicant states that the proposed site already has utilities service and is zoned, which would allow the project to be developed timelier.

Develop the Proposed MRI as a Hospital-Based Service-The applicant states that developing the proposed fixed MRI scanner in a hospital could result in temporary closures or workflow disruptions. The applicant states that a freestanding imaging facility will introduce a lower-cost, and convenient option for MRI patients.

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 will geographically enhance access to MRI services to Caswell and Warren County residents.
- The applicant's proposal will serve as a cost-effective alternative to hospital-based MRI services.
- 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.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arringdon / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arringdon.

In Section E, pages 71-72, 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:

Developing a Fixed MRI at a Different Location-The applicant states that developing the fixed MRI scanner at a different location to enhance patient access was considered. However, with the availability of existing services throughout the area and Arringdon's rapid utilization growth, the proposed location proved to be more cost effective than developing a new facility in a different location that will require duplicating resources in place at other locations.

Relocate an Existing Fixed Scanner-The applicant considered relocating an existing fixed MRI scanner from Duke Imaging Southpoint, but this alternative was dismissed because it would reduce access for patients and providers who rely on the existing equipment.

Use Mobile MRI Services at Arringdon-The applicant states that this alternative was dismissed because of the possible lack of capacity at the existing mobile MRI scanners, the additional operating costs associated with contracting with a vendor, and the vendor's scheduling constraints. Moreover, a mobile MRI scanner would not meet the need for one fixed MRI scanner in the service area.

On page 71, the applicant states that its proposal is the most effective alternative because it would meet the rapid utilization growth at Arringdon and enhance access to MRI services in the southern part of the county. Additionally, it would be more cost-effective to expand MRI services at an existing facility as opposed to developing a new imaging center.

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

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

Conclusion

The Agency reviewed the:

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

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

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

C-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

Capital and Working Capital Costs

In Section Q, page 128, the applicant projects the total capital cost of the project, as shown in the table below.

Construction/Renovation Contract(s)	\$4,090,317
Architecture/Engineering Fees	\$247,873
Medical Equipment	\$3,301,871
Non-Medical Equipment	\$26,148
Furniture	\$124,203
Consulting Fees (Preconstruction, Project Mgmt)	\$195,097
Other (Permits, IT, Security, Contingency)	\$696,388
Total	\$8,681,897

In Section Q, page 129, 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 that are based on the applicant's experience with similar projects.

In Section F, pages 82-83, the applicant projects that start-up costs will be \$70,077 and initial operating expenses will be \$315,013 for a total working capital of \$385,090. On page 83, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant states that the initial operating period represents the first five months when operating expenses exceed revenues. Initial operating expenses include all non-depreciation expenses calculated as the difference between operating expenses and revenue.
- The applicant states that start-up cost represents 30 days of supplies, utilities, salaries and benefits, and all other expenses, excluding depreciation.

Availability of Funds

In Section F, pages 81 and 85, the applicant states that the capital and working capital cost will be funded by UNC Health through accumulated reserves.

In Exhibit F-2-1, the applicant provides a letter dated October 15, 2024, from the Chief Financial Officer for UNC Health, documenting the commitment to fund the capital and working capital costs of the project through accumulated reserves. Exhibit F-2-1 includes UNC Health’s 2023 financial statements documenting over \$179 million in cash and cash equivalents and over \$3 billion in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

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 third full fiscal year following completion of the project, as shown in the table below.

	1st FFY FY 2028	2nd FFY FY 2029	3rd FFY FY 2030
Total Procedures (Adjusted)	2,216	3,092	4,134
Total Gross Revenues (Charges)	\$5,247,160	\$7,541,383	\$10,383,523
Total Net Revenue	\$1,296,695	\$1,863,651	\$2,566,010
Average Net Revenue per Procedure	\$585	\$603	\$621
Total Operating Expenses (Costs)	\$1,649,319	\$2,005,789	\$2,174,583
Average Operating Expense per Procedure	\$744	\$649	\$526
Net Income	(\$352,624)	(\$142,138)	\$391,427

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. 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
- 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 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.

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

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/Renovation Contract(s)	\$1,674,000
Architecture/Engineering Fees	\$281,000
Medical Equipment	\$3,500,000
Non-Medical Equipment and IT	\$105,000
Furniture	\$75,000
Other (Contingency)	\$320,000
Total	\$5,955,000

In Section Q, page 127, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibits F.1(a) F.1(b), the applicant provides estimates from the Architect and an equipment quote from the vendor.
- The applicant projects costs based on recent DUHS MRI projects.

In Section F, page 75, the applicant states that the project will not require an initial operating cost because the proposal includes adding services at an existing facility. The applicant projects that start-up costs will be \$31,795 for a total working capital of \$31,795. On page 75, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions that are based on the costs of additional staff, accreditation, and equipment during the first two weeks of operation.

Availability of Funds

On page 74, the applicant states that the capital and working capital costs will be funded through DUHS accumulated reserves.

In Exhibit F.2(a), the applicant provides a letter dated October 9, 2024, from the Senior Vice President for DUHS, documenting the commitment to fund the capital and working capital costs of the project through accumulated reserves. Exhibit F.2(b) includes DUHS’ 2024 financial statements documenting over \$30 million in cash and cash equivalents and over \$9 billion in total assets.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

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 fiscal years following completion of the project, as shown in the table below.

Duke Imaging Arrington	1st FFY FY 2027	2nd FFY FY 2028	3rd FFY FY 2029
Total Procedures (Adjusted)	9,820	10,138	10,735
Total Gross Revenues (Charges)	\$9,115,091	\$9,410,227	\$9,964,360
Total Net Revenue	\$4,339,191	\$4,628,442	\$5,064,369
Average Net Revenue per Procedure	\$442	\$457	\$472
Total Operating Expenses (Costs)	\$3,261,627	\$3,445,570	\$3,264,964
Average Operating Expense per Procedure	\$332	\$340	\$304
Net Income	\$1,077,564	\$1,182,872	\$1,799,405

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges.

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
- 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 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-Both Applications

On page 335, the 2024 SMFP defines the fixed MRI service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Therefore, for the purpose of this review, the fixed MRI service area is a multicounty service area: Durham, Caswell, and Warren counties. 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 Durham/Caswell/Warren multicounty fixed MRI scanner service area.

Durham/Caswell/Warren Fixed MRI Scanners			
	# of Fixed Scanners	Total MRI Scans	Adjusted Total
Duke Regional Hospital	2	10,165	13,541
Duke University Hospital	10	46,895	61,114
Duke Imaging Arringdon (Duke University Health System)	1	3,954	4,180
Durham Independence Park (Durham Diagnostic Imaging (Independence Park))	1	732	793
EmergeOrtho-Southpoint (EmergeOrtho)	1	3,027	3,047
EmergeOrtho-William Penn Plaza (EmergeOrtho)	1	4,396	4,469

Source: 2024 SMFP, Table 15E-1. Page 343

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section G, page 90, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Durham/Caswell/Warren multicounty fixed MRI scanner service area. The applicant states:

“Within the service area, UNC Durham County Imaging will represent the first freestanding diagnostic center affiliated with UNC Health in Durham County... the rapid growth and aging of the communities in the service area have driven increases in demand for outpatient MRI services, underscoring a critical need to make lower-cost, freestanding MRI services more widely available. In particular, the South region of Durham County has fewer fixed MRI scanners compared to the North and Central/West regions. By developing additional freestanding fixed MRI capacity at UNC Durham County Imaging, UNC DCI ensures that its patients will have consistent, long-term access to conveniently located, high quality, lower-cost imaging services. Additionally, the scope of services provided with the scanning capabilities of the proposed equipment, and the facility’s proximity to the approved but not yet developed UNC Hospitals-RTP community hospital enable UNC Durham County Imaging and its parent to offer access to a broader range of imaging services in both a hospital-based and freestanding setting.”

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

Conclusion

The Agency reviewed the:

- Application

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

In Section G, pages 82-83, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Durham/Caswell/Warren multicounty fixed MRI scanner service area. The applicant states:

“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... While Duke University Hospital does have a scanner under development, that additional capacity will not fully obviate the capacity constraints at DUHS facilities.

DUHS facility utilization has grown significantly despite any putative capacity at any other provider, reflecting demand for DUHS services. Additionally, the nearest fixed MRI scanner in Durham County to the proposed location is 7 miles away, and is a Duke hospital-based facility. While that facility does have some capacity, it operates older equipment and does not have sufficient availability to accommodate all of the anticipated volume at Duke Imaging Arrington. The proposed project provides an alternative cost structure and a 3.0T MRI, which is not offered at that facility.”

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

Conclusion

The Agency reviewed the:

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

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

- (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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section Q, page 134, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE		
	1 st Full FY FY 2028	2 nd Full FY FY 2029	3 rd Full FY FY 2030
MRI Technologist	1.0	2.0	2.2
Scheduler/Registration	1.0	2.0	2.2
Technologist Aid	0.5	1.2	1.3
Imaging Supervisor	1.0	1.0	1.0
Imaging Manager	0.2	0.2	0.2
Total	3.7	6.4	6.9

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.3. In Section H, pages 92-93, the applicant describes the methods to be used to recruit or fill new positions and its proposed 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 will enter into a professional service agreement with UNC Health to recruit appropriate staff and provide staff training.
- UNC Health will recruit staff through standard methods such as job postings on UNC Health’s website, attendance at job fairs, advertising in local newspapers and professional journals, and enhance recruitment efforts for critical staff positions by offering sign-on bonuses, loan forgiveness and relocation assistance.
- The applicant states that UNC Health has policies and procedures in place to ensure proper training and continuing education programs.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

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

Position	Current FTE	Projected FTE		
	As of 06/30/2024	1 st FFY FY 2028	2 nd FFY FY 2029	3 rd FFY FY 2030
MRI Technologists	4.39	7.84	7.84	7.84
Radiology Supervisor	0.96	1.12	1.12	1.12
Clinical Nurse	0.99	1.12	1.12	1.12
Orientees	0.06			
CT Technologists	1.61	2.24	2.24	2.24
Radiologic Technician	1.16	1.12	1.12	1.12
Mammography Technician	1.14	1.12	1.12	1.12
Patient Service Associate	0.92	1.12	1.12	1.12
Sonographer	1.23	2.24	2.24	2.24
Total	12.46	17.92	17.92	17.92

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 84-85, 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:

- DUHS utilizes methods such as the internet, social media, job fairs, and advertisements to recruit staff and adheres to changing market demands to recruit and retain high quality staff.
- All clinical staff are required to maintain licensure and certification appropriate to the position and attend continuing education programs.

Conclusion

The Agency reviewed the:

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

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

- (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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

Ancillary and Support Services

In Section I, page 94, the applicant identifies the necessary ancillary and support services for the proposed services. On page 94, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, page 95, the applicant describes its efforts to develop relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant will leverage UNC Health's established relationships with local healthcare and social service providers that will continue following the completion of the proposed project.
- In Exhibit I.2, the applicant provides letters from healthcare providers, documenting support for the proposed project.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

Ancillary and Support Services

In Section I, page 86, the applicant identifies the necessary ancillary and support services for the proposed services. On page 86, 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. Arrington is an existing facility with ancillary and support services already in place that will support the proposed fixed MRI scanner.

Coordination

In Section I, page 87, 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. As an established healthcare system in North Carolina, DUHS has existing relationships and collaborations with local health care and social service providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments

- Responses to comments

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

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

NA-Both Application

Neither of the applicants project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, 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-Both Applications

Neither of the applicants are 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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section K, page 98, the applicant states that the project involves renovating 8,716 square feet of existing space. Line drawings are provided in Exhibit C.1-1.

On pages 98-99, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant is proposing to lease and upfit an existing space with existing utilities and zoning. The applicant states that the proposal can be developed more cost-effectively and efficiently by avoiding cost and time associated with constructing a new building.

On page 99, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant adequately demonstrates how developing the freestanding diagnostic center will enhance access to a fixed MRI scanner for service area residents and provides a convenient, cost-effective alternative to hospital-based fixed MRI services.

In Section B, pages 29-30, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

In Section K, page 90, the applicant states that the project involves renovating 1,482 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 90, 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 worked with the architect to develop a cost-effective plan to develop the proposed fixed MRI scanner within the existing facility.
- The applicant relied on the architect's experience with similar projects regarding construction costs and design.

On page 91, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that reimbursement rates are established by Medicare, Medicaid, and/or private payor contracts.
- The applicant states that the cost to develop the project was deemed necessary and appropriate to provide services.

On page 91, 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
- Written comments
- Responses to comments

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

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

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

UNC Durham County Imaging is not an existing facility. Therefore, Criterion (13a) is not applicable to this review.

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

In Section L, page 93, the applicant provides the historical payor mix during the last full fiscal year for the proposed services, as shown in the table below.

Duke Imaging Arrington Historical Payor Mix 07/01/2023-06/30/2024	
Payor Category	Percent of Total
Self-Pay	1.1%
Charity Care	1.3%
Medicare*	35.6%
Medicaid*	4.5%
Insurance*	54.9%
Workers Compensation	0.1%
TRICARE	1.5%
Other (other govt)	1.0%
Total	100.0%

*Including any managed care plans.

In Section L, page 94, the applicant provides the following comparison.

Duke Imaging Arrington	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area Durham, Caswell, Warren Counties Combined
Female	69.0%	52.0%
Male	30.0%	48.0%
Unknown	1.0%	
64 and Younger	64.0%	16.0%
65 and Older	36.0%	84.0%
American Indian	0.4%	1.0%
Asian	8.0%	6.0%
Black or African American	20.0%	35.0%
Native Hawaiian or Pacific Islander	0.1%	<1.0%
White or Caucasian	65%	44.0%
Other Race	2.0%	3.0% (two or more)
Declined / Unavailable	1.0%	

*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>. Just enter in the name of the county.

The Agency reviewed the:

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

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

- (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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 104, the applicant states:

“...UNC Durham County Imaging, is under no federal obligation to provide uncompensated care, community service, or access to care by the medically underserved, minorities or handicapped persons. UNC DCI’s parent, UNC Health, does provide, without obligation, a considerable amount of bad debt and charity care.”

Regarding patient civil rights access complaints, in Section L, page 105, the applicant states that UNC Durham County Imaging is not an existing facility.

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 95-96, the applicant states:

“DUHS has no specific obligation under federal regulations to provide uncompensated care or 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 96, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

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

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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

In Section L, page 105, 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.

UNC Durham County Imaging Projected Payor Mix 3rd Full FY, FY 2030	
Payor Source	% of Total
Self-pay	2.6%
Charity Care [^]	
Medicare*	32.2%
Medicaid*	12.3%
Insurance*	36.9%
Other (Other Gov't, Worker's Comp ^{^^})	16.0%
Total	100.0%

*Including any managed care plans.

[^]UNC Health internal data does not include charity care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Worker's Compensation and TRICARE are included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.6% of total services will be provided to self-pay patients, 32.2% to Medicare patients and 12.3% to Medicaid patients.

On page 105, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on FY 2024 Durham County residents receiving outpatient MRI services at UNC Health facilities in Orange County.
- The applicant accounts for the anticipated shift in the percentage of self-pay to Medicaid due to North Carolina’s Medicaid expansion.

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

In Section L, page 97, 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.

Duke Imaging Arrington MRI Fixed Scanners Projected Payor Mix 3rd Full FY, FY 2029	
Payor Category	Entire Facility
Self-Pay	0.7%
Charity Care	1.1%
Medicare*	34.3%
Medicaid*	4.9%
Insurance*	55.8%
Workers Compensation	0.2%
TRICARE	2.1%
Other	0.9%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.7% of total services will be provided to self-pay patients, 1.1% to charity care patients, 34.3% to Medicare patients and 4.9% to Medicaid patients.

On page 97, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the following:

- The applicant projects payor mix based on the facility's FY 2024 experience.
- The applicant accounts for 1.6 percent adjustment from insurance volumes to Medicare volumes, due to the anticipated aging of the patient population.

The Agency reviewed the:

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

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

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

In Section L, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

In Section L, page 98, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

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

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

Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section M, pages 109-110, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- UNC Health's existing affiliations with professional training programs.
- UNC Hospitals status as an academic medical center with a history of supporting health professional training programs in the community.

Conclusion

The Agency reviewed the:

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

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

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

In Section M, page 100, 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 the following.

- Arrington is an existing facility in the service area that currently provides access for training purposes.
- The applicant states that radiology trainees will continue to participate in interpretations of procedures performed at Arrington.

Conclusion

The Agency reviewed the:

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

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

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

Both Applications

On page 335, the 2024 SMFP defines the fixed MRI service area as “... *the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1.*” Therefore, for the purpose of this review, the fixed MRI scanner service area is a multicounty service area: Durham, Caswell, and Warren counties. 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 Durham/Caswell/Warren multicounty fixed MRI scanner service area.

Durham/Caswell/Warren Fixed MRI Scanners			
	# of Fixed Scanners	Total MRI Scans	Adjusted Total
Duke Regional Hospital	2	10,165	13,541
Duke University Hospital	10	46,895	61,114
Duke Imaging Arringdon (Duke University Health System)	1	3,954	4,180
Durham Independence Park (Durham Diagnostic Imaging (Independence Park))	1	732	793
EmergeOrtho-Southpoint (EmergeOrtho)	1	3,027	3,047
EmergeOrtho-William Penn Plaza (EmergeOrtho)	1	4,396	4,469

Source: 2024 SMFP, Table 15E-1. Page 343

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 112, the applicant states:

“...UNC Durham County Imaging will be the first freestanding diagnostic center affiliated with UNC Health in Durham County and will represent an additional, affordable option for patients seeking MRI services close to home. Moreover, UNC Health is committed to serving patients from across the state and regularly provides care for patients from all 100 counties. As such, the proposed project will not only create additional fixed MRI capacity within the service area, but will increase access to high quality, lower-cost imaging services for immigrating patients as well.”

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

“As a freestanding facility, UNC Durham County Imaging will provide services that require a lower out-of-pocket cost to most patients. Insurance companies categorize hospital-based services in a higher tier than they do freestanding services, meaning that the patient’s out-of-pocket expenses typically are lower when receiving non hospital-based care. As a result, the proposed project will promote access to lower cost imaging services.

...

Additionally, UNC DCI, as part of the larger UNC Health system, benefits from significant cost savings measures through the consolidation of multiple services and large economies of scale.”

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

Regarding the impact of the proposal on quality, in Section B, page 27, the applicant states:

“UNC Health, the sole member of UNC DCI, is known for providing high quality services and expects the proposed project to provide significant benefits to patients in terms of safety, quality, access, and value through additional freestanding MRI capacity. The freestanding fixed MRI services offered at UNC Durham County Imaging will complement the diagnostic services provided at UNC Hospitals-RTP, a previously approved 112-bed community hospital to be located in southern Durham County, extending the spectrum of care provided by UNC Health facilities in the area and offering a convenient, lower-cost setting for patients to receive MRI imaging services.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section B, page 29, the applicant states:

“As North Carolina’s only state-owned, comprehensive, full-service hospital system, UNC Health has the obligation to accept any North Carolina citizen requiring medically necessary treatment. No North Carolina citizen is presently denied access to non-elective care because of race, sex, creed, age, handicap, financial status, or lack of medical insurance...As a wholly owned entity, UNC DCI will be governed by UNC Health’s policies, including those related to access to care, to guide the practices of the UNC Durham County Imaging facility.

As outlined in its ‘Assuring Access at UNC Health Care’ document, Exhibit B.20-5, UNC Health strives to provide adequate financial assistance and expand its overall capacity in order to meet the healthcare needs of all North Carolinians.”

See also Sections 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

J-12577-24 / Duke Imaging Arringdon / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arringdon.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 101, the applicant states:

“This proposal will increase MRI scanning capacity at Duke Imaging Arringdon and will increase scheduling availability for outpatient procedures. It will increase patients’ ability to choose their care based on their clinical needs, not just capacity constraints.”

DUHS would also note that the state’s MRI patient origin reports reflect that MRI patients seen at service area facilities come from across the state. Increasing capacity at DUHS will increase access and choice for patients from across the Triangle and the state, not just in the immediate service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, 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.”

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

Regarding the impact of the proposal on quality, in Section N, page 101, the applicant states:

“Decreasing wait times for procedures can reduce delays in treatment, benefitting quality of care across a range of services. Moreover, Duke Health has a national reputation for quality and safety, and this project, operated under DUHS policies and with interpretations provided by nationally renowned Duke providers, will have a positive impact on the overall quality of MRI services available in the service area.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section L, page 95, the applicant states:

“...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.”

See also Section 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- (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-Both Applications

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

In Section Q, page 136, the applicant identifies the hospitals and diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 15 hospitals and four diagnostic centers located in North Carolina. Diagnostic centers are not subject to DHSR license requirements.

In Section Q, page 114, the applicant states: “*Each of the facilities identified in Form O has continually maintained all relevant licensure, certification, and accreditation for the 18 months preceding the submission of this application.*” 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 the 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 15 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

In Section Q, Form O, the applicant identifies the hospitals and diagnostic centers located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 12 hospitals and four diagnostic centers located in North Carolina. Diagnostic centers are not subject to DHSR license requirements.

In Section O, pages 104-105, the applicant states that, during the 18 months immediately preceding the submittal of the application, DUHS is not aware of any incidents related to quality of care that has occurred in any of these facilities. However, two facilities had findings resulting in immediate jeopardy. Maria Parham Hospital was cited for immediate jeopardy on July 24, 2024. Wilson Medical Center was cited for immediate jeopardy on March 15, 2023 and August 24, 2024. The applicant states that all the problems have been corrected. 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, three facilities had Emergency Medical Treatment and Labor Act (EMTALA) citations that are currently pending final decisions. After reviewing and considering the 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 12 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-Both Applications

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

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

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire a fixed MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*
(1) *identify the existing fixed MRI scanners owned or operated by the applicant or a related entity and located in the proposed fixed MRI scanner service area;*

-NA- **UNC Durham County Imaging.** In Section C, page 66, the applicant states UNC DCI does not currently own or operate any fixed MRI scanners in the fixed MRI scanner service area.

-C- **Duke Imaging Arrington.** In Section B, page 62, the applicant states DUHS, operates 14 fixed MRI scanners in the proposed 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- **UNC Durham County Imaging.** In Section C, page 67, the applicant states that there are no approved fixed MRI scanners that it owns or operates in the proposed fixed MRI scanner service area.

-C- **Duke Imaging Arrington.** In Section C, page 63, the applicant identified one approved fixed MRI scanner that it owns in the proposed fixed MRI scanner service area; Project ID# J-12463-23.

(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- **UNC Durham County Imaging.** In Section C, page 67, the applicant states that neither the applicant nor any related entity owns or operates a mobile MRI scanner in the proposed fixed MRI scanner service area.
- C- **Duke Imaging Arrington.** In Section C, page 63, the applicant identified one existing mobile MRI scanner that it owns and operates at Duke Regional Hospital in the proposed fixed MRI scanner service area
 - (4) *identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area;*
- NA- **UNC Durham County Imaging.** In Section C, page 67, the applicant states that neither the applicant nor any related entity has been approved to own or operate a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.
- NA- **Duke Imaging Arrington.** In this application, the applicant does not identify any approved mobile MRI scanners owned or operated by the applicant in the proposed fixed MRI scanner service area.
 - (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;*
- C- **UNC Durham County Imaging.** In Section Q, page 119, the applicant provides projected utilization for its proposed fixed MRI scanner during each of the first three full fiscal years of operation following project completion.
- C- **Duke Imaging Arrington.** In Section Q, pages 112-119, the applicant provides projected utilization for its existing fixed MRI scanners in Durham 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- **UNC Durham County Imaging.** In Section Q, pages 121-127, the applicant provides projected utilization of the proposed fixed MRI scanner through the first three full fiscal years of operation following project completion.
- C- **Duke Imaging Arrington.** In Section Q, pages 116-125, 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 (a)(1) and (a)(2) of this Paragraph and the proposed fixed MRI scanner shall perform during the third full fiscal year of operation following completion of the project as follows:*

- (a) *3494 or more adjusted MRI procedures per MRI scanner if there are two or more fixed MRI scanners in the fixed MRI scanner service area;*
- (b) *3058 or more adjusted MRI procedures per MRI scanner if there is one fixed MRI scanner in the fixed MRI scanner service area; or*
- (c) *1310 or more adjusted MRI procedures per MRI scanner if there are no existing fixed MRI scanners in the fixed MRI scanner service area; and*

According to Table 15E-1, page 343 of the 2024 SMFP, there are currently 16 existing fixed MRI scanners in the Durham/Caswell/Warren multicounty fixed MRI scanner service area. All of the scanners are located in Durham County. Therefore, Subparagraph (a) applies to this review.

-C- **UNC Durham County Imaging.** In Section Q, page 119, the applicant projects to provide 4,134 adjusted MRI procedures on the proposed fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

-C- **Duke Imaging Arrington.** In Section Q, page 112-114, the applicant projects to provide more than 3,494 adjusted MRI procedures per fixed MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(8) *Project that the mobile MRI scanners identified in Subparagraphs (3) and (4) of this Paragraph shall perform 3120 or more adjusted MRI procedures per mobile MRI scanner during the third full fiscal year of [operation following] completion of the proposed project.*

-NA- **UNC Durham County Imaging.** Neither the applicant nor any related entity owns or operates a mobile MRI scanner that will provide mobile MRI services at host sites located in the proposed fixed MRI scanner service area.

-C- **Duke Imaging Arrington.** In Section Q, page 115, the applicant projects to provide 4,421 adjusted mobile MRI procedures per mobile MRI scanner during the third full fiscal year of operation following project completion. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(b) *An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

(1) *identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI*

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

- (2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- (4) identify the approved fixed MRI scanners owned or operated by the applicant or a related entity that will be located in the proposed mobile MRI scanner service area;*
- (5) identify the existing and proposed host sites for each mobile MRI scanner identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner;*
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three full fiscal years of operation following completion of the project;*
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*
- (8) project that the mobile MRI scanners identified in Subparagraphs (b)(1) and (b)(2) of this Paragraph and the proposed mobile MRI scanner shall perform 3120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and*
- (9) project that the fixed MRI scanners identified in Subparagraphs (b)(3) and (b)(4) of this Paragraph shall perform during the third full fiscal year of operations following completion of the project:*
 - (a) 3494 or more adjusted MRI procedures per fixed MRI scanner if there are four or more fixed MRI scanners in the fixed MRI scanner service area;*
 - (b) 3058 or more adjusted MRI procedures per fixed MRI scanner if there are three fixed MRI scanners in the fixed MRI scanner service area;*
 - (c) 1310 or more adjusted MRI procedures per MRI scanner if there are two fixed MRI scanners in the fixed MRI scanner service area;*

-NA- **UNC Durham County Imaging.** The applicant does not propose to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period.

-NA- **Duke Imaging Arrington.** 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.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2024 State Medical Facilities Plan, no more than one fixed MRI scanner may be approved for the Durham/Caswell/Warren multicounty fixed MRI scanner Service Area in this review. Because both applications in this review collectively propose to develop two additional fixed MRI scanners to be located in the Durham/Caswell/Warren multicounty fixed MRI scanner service area, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of both of the proposals to decide which proposal should be approved.

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

J-12576-24 / UNC Durham County Imaging / Acquire one fixed MRI scanner

The applicant proposes to acquire one fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at a new diagnostic center.

J-12577-24 / Duke Imaging Arrington / Acquire one fixed MRI scanner

The applicant proposes to acquire an additional fixed MRI scanner pursuant to the need determination in the 2024 SMFP to be located at Duke Imaging Arrington.

Conformity with Statutory and Regulatory Review Criteria

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

Geographic Accessibility (Location within the Service Area)

There are 16 existing fixed MRI scanners located in Durham County. Three of the existing fixed MRI scanners are located in southern Durham County, including two fixed MRI scanners in Morrisville, and one fixed MRI scanner located in the Southpoint area. The remaining fixed MRI scanners are located in the city of Durham. Both applications in this review propose to locate the fixed MRI scanner in diagnostic centers in southern Durham County, approximately five miles and nine minutes driving time apart from each other. Therefore, both applications are equally effective alternatives with regard to this comparative factor.

Access by Underserved Groups

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

“Medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the

proposed services, particularly those needs identified in the State Health Plan as deserving of priority.”

For access by underserved groups, applications are compared with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicare

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

MRI Services to Medicare Patients 3rd Project Year			
Applicant	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
UNC Durham County Imaging	\$3,339,031	\$10,383,523	32%
Duke Imaging Arrington	\$3,421,041	\$9,964,360	34%

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **UNC Durham County Imaging** projects that 32% of its fixed MRI services will be provided to Medicare patients. The application submitted by **Duke Imaging Arrington** projects that 34% of its fixed MRI services will be provided to Medicare patients. Therefore, with regard to projected access for Medicare patients, the application submitted by **Duke Imaging Arrington** is the more effective alternative.

Projected Medicaid

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

MRI Services to Medicaid Patients 3rd Project Year			
Applicant	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
UNC Durham County Imaging	\$1,278,384	\$10,383,523	12%
Duke Imaging Arrington	\$488,547	\$9,964,360	5%

Source: Form F.2b for each applicant.

As shown in the table above, the application submitted by **UNC Durham County Imaging** projects that 12% of its MRI services will be provided to Medicaid patients. The application submitted by **Duke Imaging Arrington** projects that 5% of its fixed MRI services will be provided to Medicaid patients. Therefore, with regard to projected access for Medicaid patients, the application submitted by **UNC Durham County Imaging** is the more effective alternative.

Competition (Access to a New or Alternate Provider)

The following table shows the existing providers of fixed MRI scanner services located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

Durham/Caswell/Warren Fixed MRI Scanners			
	# of Fixed Scanners	Total MRI Scans	Adjusted Total
Duke Regional Hospital	2	10,165	13,541
Duke University Hospital	10	46,895	61,114
Duke Imaging Arrington (Duke University Health System)	1	3,954	4,180
Durham Independence Park (Durham Diagnostic Imaging (Independence Park))	1	732	793
EmergeOrtho-Southpoint (EmergeOrtho)	1	3,027	3,047
EmergeOrtho-William Penn Plaza (EmergeOrtho)	1	4,396	4,469

Source: 2024 SMFP, Table 15E-1. Page 343

As shown in the table above, **DUHS** owns and operates the majority of fixed MRI scanners operating in the service area, including the proposed MRI scanner to be located at **Duke Imaging Arrington**. **UNC Durham County Imaging** is proposing to develop a new diagnostic center offering MRI services in the service area. Therefore, with regard to patient access to a new or alternate provider, **UNC Durham County Imaging** is the more effective alternative.

Projected Average Net Revenue per Adjusted MRI Procedure

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

Projected Average Net Revenue per Adjusted MRI Procedure 3rd Project Year			
Applicant	Net Revenue	Adjusted MRI Procedures	Average Net Revenue / Adjusted MRI Procedure
UNC Durham County Imaging	\$2,566,010	4,134	\$621
Duke Imaging Arrington	\$5,064,369	10,735	\$472

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

As shown in the table above, the application submitted by **Duke Imaging Arrington** projects the lowest average net revenue per adjusted MRI procedure in the third operating year. Therefore, regarding projected average net revenue per adjusted MRI procedure in the third project year, the application submitted by **Duke Imaging Arrington** is the more effective alternative.

Projected Average Operating Expense per Adjusted MRI Procedure

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

Projected Average Total Operating Expenses per Adjusted MRI Procedure 3rd Project Year			
Applicant	Operating Expense	Adjusted MRI Procedures	Average Operating Expenses / Adjusted MRI Procedure
UNC Durham County Imaging	\$2,174,583	4,134	\$526
Duke Imaging Arrington	\$3,264,964	10,735	\$304

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

As shown in the table above, the application submitted by **Duke Imaging Arrington** projects the lowest average operating expense per adjusted MRI procedure in the third operating year. Therefore, the application submitted by **Duke Imaging Arrington** is the most effective application with respect to projected average operating expense per adjusted MRI procedure.

Summary

The following table lists the comparative factors and indicates whether each application was more effective or less effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	UNC Durham County Imaging	Duke Imaging Arrington
Conformity with Statutory Review Criteria	Equally Effective	Equally Effective
Geographic Accessibility (location within the SA)	Equally Effective	Equally Effective
Access by Medicare Patients	Less Effective	More Effective
Access by Medicaid Patients	More Effective	less Effective
Competition (access to a new or alternative provider)	More Effective	Less Effective
Average Net Revenue per Adjusted MRI Procedure	Less Effective	More Effective
Average Operating Expense per Adjusted MRI Procedure	Less Effective	More Effective

Both applications submitted are conforming to all applicable statutory and regulatory review criteria, and thus both applications are approvable standing alone. However, collectively they propose a total of two fixed MRI scanners in the Durham/Caswell/Warren Multicounty fixed MRI scanner service area, but the need determination in the 2024 SMFP is for only one fixed MRI scanner. Therefore, only one fixed MRI scanner in the service area can be approved.

As shown in the table above, the application submitted by **UNC Durham County Imaging** was determined to be a more effective alternative for the following two factors:

- Access by Medicaid Patients
- Competition

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

- Access by Medicare Patients
- Average Net Revenue per Adjusted MRI Procedure
- Average Operating Expense per Adjusted MRI Procedure

DECISION

Each application is individually conforming to the need determination in the 2024 SMFP for one fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area, as well as individually conforming to all statutory and regulatory review criteria. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Duke Imaging Arrington** is the more effective alternative proposed in this review for the development of one additional fixed MRI scanner in the Durham/Caswell/Warren multicounty fixed MRI scanner service area pursuant to the need determination in the 2024 SMFP and is approved. The application submitted by **UNC Durham County Imaging** is denied.

The application submitted by **Duke Imaging Arrington** is approved subject to the following conditions:

- 1. Duke University Health System, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to the need determination in the 2024 SMFP for a total of three fixed MRI scanners at Duke Imaging Arrington.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on November 3, 2025.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. The certificate holder shall 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.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**