Comments on Competing Application for One Additional Fixed MRI Scanner in Durham County

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submitted by

UNC DCI, LLC

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), UNC DCI, LLC (UNC DCI)[1] hereby submits the following comments related to the competing application submitted by Duke University Health System Inc. ("DUHS") to develop a fixed MRI scanner at its existing diagnostic center, Duke Imaging Arringdon (Project ID # J-012577-24) in response to the need determination for one fixed MRI scanner in the Durham/Caswell/Warren multicounty service area in the *2024 State Medical Facilities Plan (2024 SMFP*). UNC DCI's comments on DUHS's competing application include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards."[2] *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, UNC DCI has identified the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria creating the non-conformity in the DUHS application.

[1] Please note that UNC DCI, LLC is wholly owned by UNC Health.

[2] UNC DCI is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to the application filed on October 15, 2024 by UNC DCI (Project ID # J-012576-24).

APPLICATION-SPECIFIC COMMENTS

UNC DCI believes that DUHS's application contains methodological flaws that invalidate its analysis of the need for its proposed services. As a result of these flaws, its application is non-conforming with multiple statutory and regulatory review criteria, and as such the application is not approvable.

As background, DUHS's existing diagnostic center and the proposed location of the additional fixed MRI scanner, Duke Imaging Arringdon, currently operates two fixed MRI scanners. While the *Proposed 2025 SMFP* lists only one fixed MRI scanner at Duke Imaging Arringdon,[3] DUHS itself notes that it currently operates two fixed MRI scanners at that diagnostic facility, the second of which was operationalized earlier in 2024.[4] As such, DUHS's projections, as well as the discussion contained herein, assume that Duke Imaging Arringdon has available capacity represented by its two existing fixed MRI scanners, and that, if DUHS's proposed application were approved, it would operate three total fixed MRI scanners.

The DUHS application does not demonstrate the need for a third MRI scanner at its Arringdon facility.

In its "Form C.2a and C.2b Utilization – Assumptions and Methodology," DUHS projects that Duke Imaging Arringdon will perform the following number of MRI scans at Duke Imaging Arringdon through fiscal year (FY) 2029, the third year following development of its proposed project:

Projected Adjusted MRI Volumes -- Arringdon MRI

	FY 2025	FY 2026	FY 2027	FY 2028	FY 2029
Arringdon Volumes (unadjusted)	6,308	6,609	9,080	9,374	9,926
Arringdon Volumes (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: Project ID # J-012577-24, pp. 119-120.

In other words, Duke Imaging Arringdon is projected to perform 9,926 unadjusted MRI scans in FY 2029 across its three fixed MRI scanners. While these projections may be intended to meet the minimum performance standards in the CON rules, they do not, however, demonstrate a need for an additional MRI scanner when contrasted with historical projections of MRI volume at Duke Imaging Arringdon.

In 2020, DUHS submitted a CON application to develop one fixed MRI scanner at Duke Imaging Arringdon (Project ID # J-011913-20), an application that was ultimately approved.[5] In that application, DUHS provided projected unadjusted MRI volume for its then-two existing and proposed fixed MRI scanners:

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3 *Proposed 2025 SMFP,* p. 343.

4 Project ID # J-012577-24, p. 25, 53, 62, and elsewhere.

5 See "Required State Agency Findings – Duke Health Arringdon Radiology," October 8, 2020, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2020/oct/findings/2020-Durham-J-11913-20-Duke-Health-Arringdon-Radiology-190274-Findings.pdf.

		FY2021	FY2022	FY2023	FY2024	FY2025
MRI 1 Volume -Go-Live 4/1/2021		623	1,925	3,209	4,543	4,543
MRI 2 Volume -Go-Live 9/1/2021		-	1,604	2,995	4,321	4,543
Total MRI Service Line Volume		623	3,529	6,204	8,864	9,086

Source: Project ID # J-011913-20, p. 85 of PDF of application.

As shown in the table above, DUHS projected that it would perform 9,086 total unadjusted MRI scans across its two existing and proposed fixed MRI scanners in FY 2025, the third year following development of the proposed MRI scanner. The second Arringdon MRI scanner has since become operational. Notably, DUHS also utilized this projected unadjusted fixed MRI scanner volume at Duke Imaging Arringdon in its 2023 CON application[6] to acquire and operate one mobile MRI scanner to serve Alamance, Durham, and Wake counties (Project ID # J-012378-23), an application that was also approved.[7]

In other words, the difference between the 9,086 projected MRI scans at Duke Imaging Arringdon in FY 2025 and the 9,926 projected MRI scans at Duke Imaging Arringdon in FY 2029 with the proposed additional third MRI scanner does not sufficiently justify the need for the MRI scanner proposed in DUHS's current application. Based upon these figures, the proposed fixed MRI scanner will account for fewer than 1,000 additional unadjusted MRI scans at Duke Imaging Arringdon (9,926 – 9,086 = 840 unadjusted MRI scans). Since DUHS previously assumed that it could perform over 4,500 unadjusted MRI scans per scanner, it is reasonable to assume that each scanner could perform just a few hundred more scans each, or 4,963 unweighted MRI scans each, for a total of 9,926 MRI scans. This is the total that DUHS projects for project year three of its current project, as shown previously.

Other recent DUHS applications also reflect DUHS's expectation that two MRI scanners can easily perform just a few hundred scans less than what now, according to DUHS's assertion, requires a third scanner to perform. In its 2023 CON application to acquire one fixed MRI scanner at Duke University Hospital in Durham County (Project ID # J-012436-23), DUHS projected a similar total of total MRI scans at Duke Imaging Arringdon in FY 2028, projecting 8,972 procedures and 9,534 weighted procedures at Duke Imaging Arringdon in FY 2028. These projections were replicated in the Agency Findings for that application, shown below:

[6] See Project ID # J-012378-23, pp. 130-131, which notes that "[f]or purposes of projecting MRI utilization for the existing and approved fixed MRI scanners…DUHS reasonably adopted the MRI utilization projections for the two fixed MRI scanners at Duke Imaging Arringdon per Project ID J-11913-20."

[7] See "Required State Agency Findings – 2023 Statewide Mobile MRI Scanner Review," October 4, 2023, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2023/sept/findings/2023%20Statewide%20Mobile%20MRI%20Findings.pdf.

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

Source: "Required State Agency Findings – Duke University Hospital Project ID # J-12436-23," April 4, 2024, p. 8, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2024/mar/findings/2023%20Durham%20J-12436-23%20Duke%20University%20Hospital%20943138%20Findings.pdf. Please also see Section Q of Project ID # J-012436-23.

Yet again, when considering the projected total MRI volume at Duke Imaging Arringdon in DUHS's current application, the proposed third fixed MRI scanner at Duke Imaging Arringdon will account for fewer than 1,000 additional MRI scans than previously projected at that facility.

Given this low volume of incremental MRI scans to be performed at that facility, UNC DCI believes that DUHS, in addition to not properly identifying the need for the proposed fixed MRI scanner, has neither identified nor appropriately considered all alternatives that are either more effective or less costly than the proposed project. Currently, Duke Imaging Arringdon operates Monday through Friday from 7:30 AM to 5:30 PM.[8] As such, it has the availability to expand its existing hours, either into the evenings on weekdays or through operating its existing MRI services on weekends. This alternative would ultimately be less costly than the development of DUHS's proposed project, which has a projected capital cost of nearly $6 million.[9] Even assuming that the two existing scanners cannot accommodate the approximately 1,000 projected incremental MRI scans, just a minor addition of a few hours of operation per week could easily accommodate the additional volume that DUHS projects for the Duke Imaging Arringdon facility.

In short, by maintaining the two existing MRI scanners at Duke Imaging Arringdon, DUHS can still accommodate its projected MRI volume, while obviating the need to expand additional capital for another MRI scanner and the construction required to make it operational.

Given these issues, DUHS's application is non-conforming with multiple statutory review criteria, including Criteria 1, 3, 4, 5, 6, 12, and 18a. As such, DUHS's application for one additional fixed MRI scanner at Duke Imaging Arringdon should not be approved.

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8 As noted on Duke Health's information page for Duke Imaging Arringdon, accessed October 28, 2024, at https://www.dukehealth.org/locations/duke-imaging-arringdon-freestanding.

9 Project ID # J-012577-24, p. 20.

COMPARATIVE ANALYSIS

As stated above, UNC DCI believes that DUHS's application is non-conforming with multiple statutory criteria and should not be approved. Further, UNC DCI believes that its application will better serve the patients of Durham, Caswell, and Warren counties by providing accessible and cost-effective freestanding MRI services in the service area.

Given that both UNC DCI and DUHS's applications propose to develop an additional fixed MRI scanner in the service area in response to the need determination in the *2024 SMFP* for one MRI scanner, only one application can be approved. To determine the comparative factors that are applicable in this review, UNC DCI examined the recent Agency findings for competitive MRI reviews. In particular, it examined the Required State Agency Findings for the need for one fixed MRI scanner in Johnston County via a need determination in the *2024 SMFP*, the most recent Agency findings for a competitive MRI application as of the submission of these comments.[10] In those findings, the following comparative factors were utilized:

- Conformity with Statutory Review Criteria
- Geographic Accessibility (Location within the Service Area)
- Access by Medicare Patients
- Access by Medicaid Patients
- Competition
- Average Net Revenue per Adjusted MRI Procedure
- Average Operating Expense per Adjusted MRI Procedure[11]

Given the particular circumstances of this review, UNC DCI believes that the factors listed above and discussed in turn below should be used by the Agency in reviewing the competing applications.

Conformity with Statutory Review Criteria

As noted above, DUHS's application is non-conforming with at least statutory review criteria 1, 3, 4, 5, 6, 12, and 18a, while UNC DCI's application is conforming with all statutory review criteria. As such, the UNC DCI application is more effective for this comparative factor.

Geographic Accessibility (Location within the Service Area)

Both DUHS and UNC DCI propose to locate the fixed MRI scanner in Durham County – specifically, southern Durham County. Duke Imaging Arringdon is located in Morrisville, a town with boundaries in both Durham County and Wake County.[12] UNC Durham County Imaging, the diagnostic center that will be developed through the addition of the proposed fixed MRI scanner, is located in Durham.[13] The following map shows the location of the existing and proposed MRI scanners in Durham County as well as the location of the approved UNC Hospitals-RTP.

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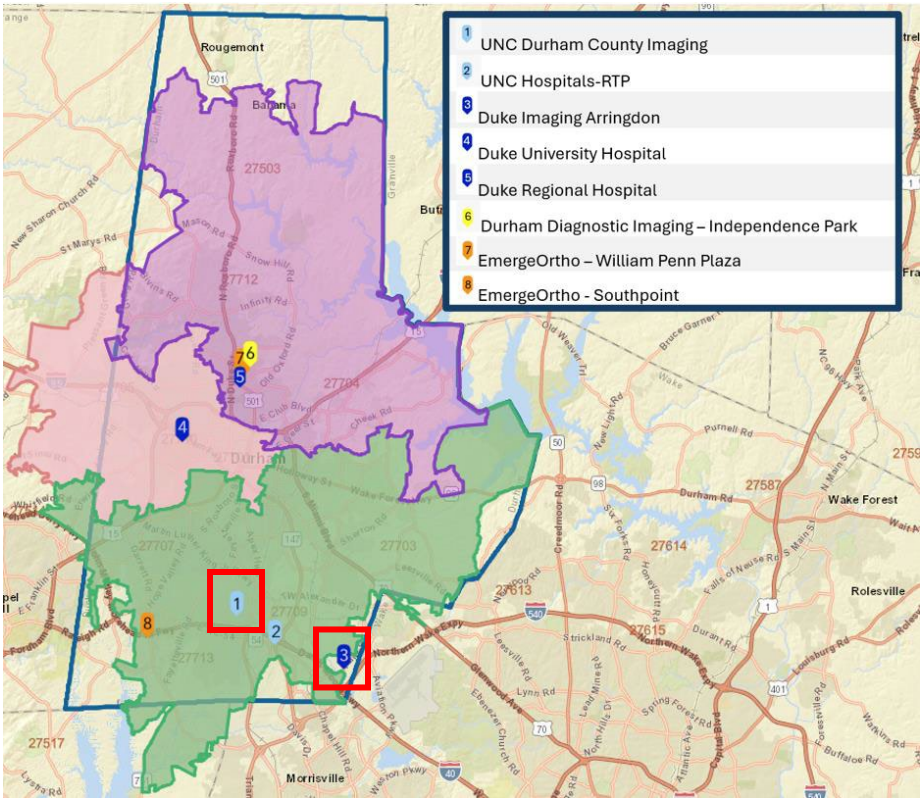
10 "Required State Agency Findings – 2024 Johnston County MRI," September 20, 2024, accessed at https://info.ncdhhs.gov/dhsr/coneed/decisions/2024/sept/findings/2024%20Johnston%20County%20Competitive%20MRI%20Findings.pdf.

11 Ibid, p. 56.

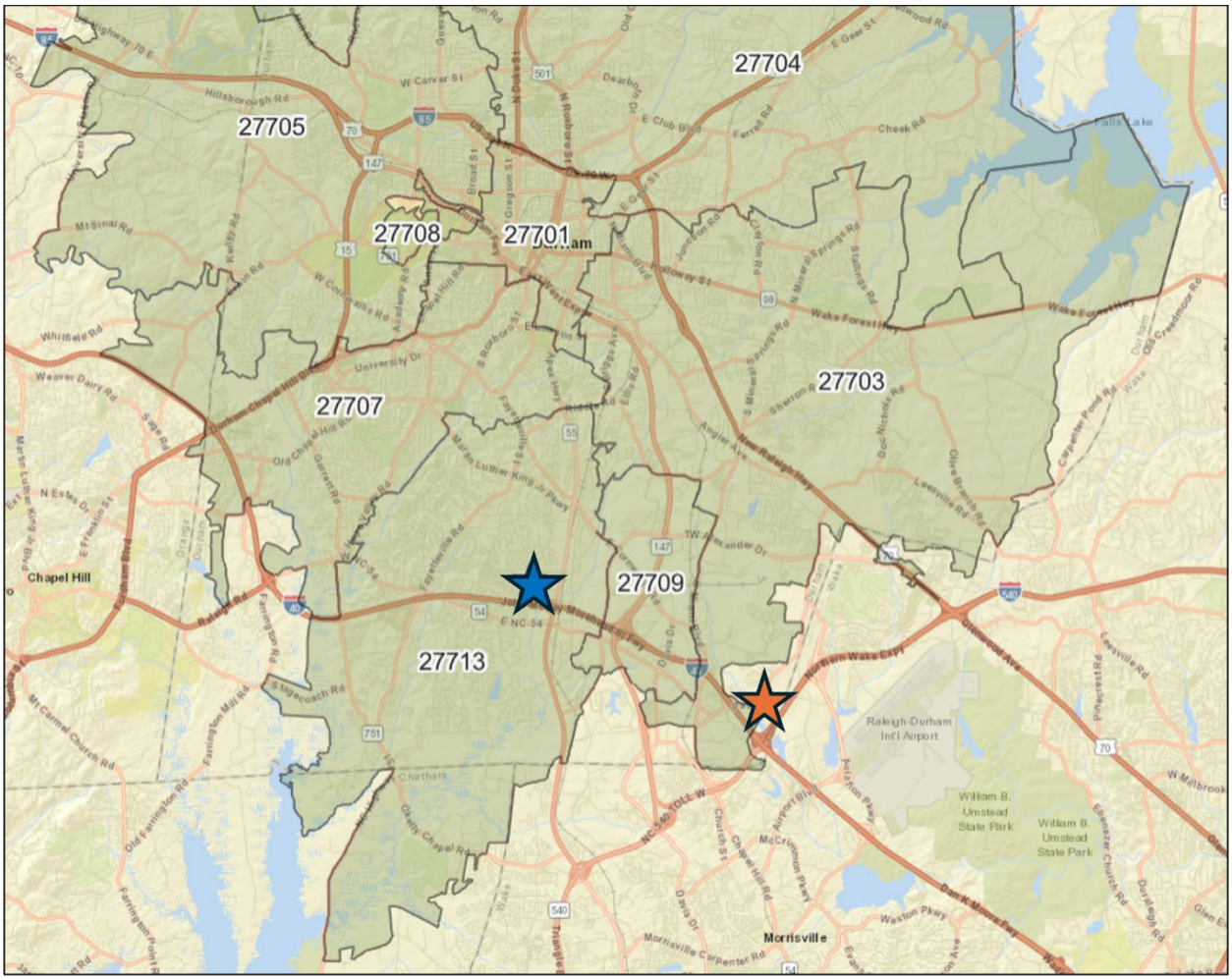
12 Project ID # J-012577-24, p. 20.

13 Project ID # J-012576-24, p. 18.



Source: Esri. Also see Project ID # J-012576-24, p. 54.

The proposed fixed MRI scanner at UNC Durham County Imaging will be located in ZIP code 27713; Duke Imaging Arringdon's street address is in ZIP code 27560, a ZIP code located primarily in Wake County; however, the most proximate Durham County ZIP codes to Duke Imaging Arringdon are 27709 and 27703, as shown in the map below.



Duke Imaging Arringdon

UNC Durham County Imaging

As discussed in UNC DCI's CON application, the southern region of Durham County is growing particularly quickly, and the ZIP code of 27713 is currently the second-most populated ZIP code in Durham County's southern region. By contrast, DUHS's proposed site is located on the border of Durham County, outside of the ZIP codes that are primarily in Durham County.

As stated above, the service area for the *2024 SMFP* need determination to which both applicants have responded is the Durham/Caswell/Warren multicounty service area; therefore, the applicant that proposes to provide the most accessible services for patients from that service area is the more effective alternative. Given that the proposed location of UNC Durham County Imaging is more centrally located to the Durham County population than Duke Imaging Arringdon, and because Duke's Arringdon imaging facility already has two approved MRI scanners, the UNC DCI application is more effective at expanding geographic access to MRI services in the service area.

Access by Medicare Patients

The table below compares access by Medicare patients in project year three for both applicants:

Medicare Revenue – Project Year 3

Applicant	*Projected Medicare Gross Revenue*	*Weighted MRI Scans*	*Medicare Revenue per Weighted MRI Scan**	*Total Gross Revenue*	*Projected Medicare % of Gross Revenue***
DUHS	$3,421,041	10,735	$319	$9,964,360	34.3%
UNC DCI	$3,339,031	4,134	$808	$10,383,523	32.2%

Source: Forms C.2b and F.2b of respective applications.
* Medicare Revenue per Weighted MRI Scan = Projected Medicare Gross Revenue ÷ Weighted MRI Scans
** Projected Medicare % of Gross Revenue = Projected Medicare Gross Revenue ÷ Total Gross Revenue

Historically, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.[14] As shown above, DUHS projects a slightly higher amount of gross revenue for Medicare patients, as well as a slightly higher percentage of total gross revenue attributed to Medicare patients. However, UNC DCI projects more Medicare revenue per weighted MRI scan. As such, the two applications are equally effective for this factor. However, the DUHS application is non-conforming with multiple review criteria, and therefore cannot be approved.

Access by Medicaid Patients

The table below compares access by Medicaid patients in project year three for both applicants:

Medicaid Revenue – Project Year 3

Applicant	*Projected Medicaid Gross Revenue*	*Weighted MRI Scans*	*Medicaid Revenue per Weighted MRI Scan**	*Total Gross Revenue*	*Projected Medicaid % of Gross Revenue***
DUHS	$488,547	10,735	$46	$9,964,360	4.9%
UNC DCI	$1,278,384	4,134	$309	$10,383,523	12.3%

Source: Forms C.2b and F.2b of respective applications.
* Medicaid Revenue per Weighted MRI Scan = Projected Medicaid Gross Revenue ÷ Weighted MRI Scans
** Projected Medicaid % of Gross Revenue = Projected Medicaid Gross Revenue ÷ Total Gross Revenue

Historically, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regards to this comparative factor.[15] As shown above, UNC DCI projects a higher amount of gross revenue for Medicaid patients, higher Medicaid revenue per weighed MRI scan, as well as a higher percentage of total gross revenue attributable to Medicaid patients. As such, the UNC DCI application is more effective for this comparative factor.

[14] Ibid, p. 54.
[15] Ibid.

Competition

The Agency has noted historically that "[g]enerally, the introduction of a new provider in the service area would be the most effective alternative."[16] DUHS is an existing provider of MRI services in Durham County, controlling 14 of the 17 existing fixed MRI scanners (82 percent), including two fixed MRI scanners at Duke Imaging Arringdon. By contrast, UNC DCI is not an existing provider of MRI services in the service area. As such, the UNC DCI application is the more effective alternative for this comparative factor.

Average Net Revenue per Adjusted MRI Procedure

The following table summarizes the gross revenue and net revenue for the MRI service at Duke Arringdon and UNC DCI, respectively, using figures from the CON applications. The DUHS figures include the proposed and existing MRI scanners at the Arringdon facility.

Average Net Revenue per Adjusted MRI Procedure – Project Year 3

Applicant	*Total Gross Revenue*	*Total Net Revenue*	*Weighted MRI Scans*	*Net Revenue per Adj. Procedure*
DUHS	$9,964,360	$5,064,369	10,735	$472
UNC DCI	$10,383,523	$2,566,010	4,134	$621

Source: Forms C.2b and F.2b of respective applications.

Based on this information, DUHS has a lower net revenue per adjusted procedure, with an average of $472, compared to UNC DCI's average net revenue per adjusted procedure of $621. However, the DUHS application is non-conforming with multiple review criteria, and therefore cannot be approved. Moreover, the projected revenue per procedure reflects the different types of MRI procedures projected by the applicants, and the difference in the mix of procedures may make this comparison of little value.

Average Operating Expense per Adjusted MRI Procedure

The following table summarizes the average operating expense per adjusted MRI scan for the MRI service at Duke Arringdon and UNC DCI, respectively, using figures from the CON applications. The DUHS figures include the proposed and existing MRI scanners at the Arringdon facility.

Average Expense per Adjusted MRI Procedure – Project Year 3

Applicant	*Total Operating Expense*	*Weighted MRI Scans*	*Operating Expense per Adj. Procedure*
DUHS	$3,264,964	10,735	$304
UNC DCI	$2,174,583	4,134	$526

Source: Forms C.2b and F.2b of respective applications.

Based on this information, DUHS has a lower operating expense per adjusted procedure, with an average of $304, compared to UNC DCI's average net revenue per adjusted procedure of $526. However, the DUHS application is non-conforming with multiple review criteria, and therefore cannot be approved. Moreover, the DUHS project proposes to add a third MRI scanner at an existing imaging facility and will be able to

[16] Ibid, p. 55.

economize on operational costs by having co-located services and non-clinical staffing coverage that supports all three of the MRI scanners. Form H of the DUHS application projects that the third MRI scanner will require just 5.46 additional FTEs due to the established presence of the Arringdon independent diagnostic testing facility (IDTF). In its Form F.2/F.3 operating cost assumptions on pages 128-130, DUHS states that some equipment at the facility will be fully depreciated during the project years, therefore resulting in diminished overall operating costs that will benefit the proposed third scanner. Some facility expenses such as housekeeping, laundry, and utilities will also be contracted for the entire facility and a percentage will be allocated to the MRI service component. In contrast, the UNC DCI application represents a new facility with one MRI scanner, and as such will have more associated costs at the proposed location. For these reasons, comparing the operating costs between the two projects is inconclusive and this factor should not be evaluated as a basis for finding the more effective applicant.

Summary of Comparative Analysis

The following table summarizes the comparative analysis for the competing applications:

Comparative Factor	*DUHS*	*UNC DCI*
Conformity with Statutory Review Criteria	No	**Yes**
Geographic Accessibility (location within the SA)	Less Effective	**More Effective**
Access by Medicare Patients	Equally Effective, but Non-Conforming	Equally Effective
Access by Medicaid Patients	Less Effective	**More Effective**
Competition	Less Effective	**More Effective**
Average Net Revenue per Adjusted MRI Procedure	More Effective, but Non-Conforming	Effective
Average Operating Expense per Adjusted MRI Procedure	Inconclusive	Inconclusive

As shown above, UNC DCI is the more effective alternative for three comparative factors, DUHS is the more effective alternative for one comparative factor, and at least one comparative factor is inconclusive. Additionally, UNC DCI is conforming with all applicable statutory review criteria, while DUHS is non-conforming with multiple statutory review criteria, including at least Criteria 1, 3, 4, 5, 6, 12, and 18a. As such, the UNC DCI application is the most effective application for the one fixed MRI scanner as determined through the need determination in the *2024 SMFP*, and its application should be approved.