



**COMPETITIVE COMMENTS ON
2023 WAKE COUNTY FIXED MRI NEED DETERMINATION
SUBMITTED BY DUKE UNIVERSITY HEALTH SYSTEM, INC.**

July 31, 2023

Three applicants submitted CON applications in response to the need identified in the 2023 SMFP for one additional fixed MRI scanner in Wake County.

- J-012393-23 Raleigh Radiology Knightdale
- J-012395-23 Duke Imaging Garner
- J-012396-23 WR Imaging, LLC

These comments are submitted by Duke University Health System, Inc. (DUHS) in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the competing applications, including a comparative analysis and a discussion of the most significant issues regarding the applicants' conformity with the statutory and regulatory review criteria ("the Criteria") in N.C. Gen. Stat. §131E-183(a) and (b). Other non-conformities in the competing applications may exist and DUHS reserves the right to develop additional opinions, as appropriate upon further review and analysis.

COMPARATIVE ANALYSIS FOR FIXED MRI SCANNERS

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than one fixed MRI scanner can be approved in Wake County in this review. Because each applicant proposes to acquire one fixed MRI scanner for a total of three MRI scanners, only one of the applications can be approved. Therefore, DUHS has prepared a comparative analysis of the proposals to determine which proposal is the most effective. The following factors are typically utilized by the Agency in competitive reviews regardless of type of services or equipment proposed:

- Conformity with Statutory and Regulatory Review Criteria
- Scope of Services
- Historical Utilization
- Geographic Accessibility (Location within the Service Area)
- Access by Service Area Residents
- Access by Underserved Groups: Charity Care
- Access by Underserved Groups: Medicaid
- Access by Underserved Groups: Medicare
- Competition (Access to a New or Alternate Provider)
- Projected Average Net Revenue per Patient/Procedure
- Projected Average Total Operating Cost per Patient/Procedure

Other comparative factors may be utilized based on the facts of the competitive review. The following summarizes the competing applications relative to the potential comparative factors.

Conformity to CON Review Criteria

Three CON applications have been submitted seeking to develop a fixed MRI scanner in Wake County. The applicants collectively propose to develop three mobile MRI scanners. Based on the 2023 SMFP’s need determination, only one (1) fixed MRI scanner can be approved. Only applicant demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by DUHS demonstrate conformity to all Criteria:

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
Duke Imaging Mobile MRI	J-012378-23	Yes
Raleigh Radiology Knightdale	J-012393-23	No
Wake Radiology Cary	J-012396-23	No

The DUHS application is based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed separately in this document, the competing applications contain errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the **DUHS** application is the most effective alternative regarding conformity with applicable review Criteria.

Scope of Services

Generally, the application proposing to provide the greatest scope of services is the more effective alternative with regard to this comparative factor.

The following table summarizes the scope of patient services proposed by each applicant.

Applicant	Hospital Based or Freestanding
Duke Imaging Mobile MRI	Freestanding
Raleigh Radiology Knightdale	Freestanding
Wake Radiology Cary	Freestanding

All of the applicants propose to acquire and operate a fixed MRI scanner in a freestanding outpatient setting. As discussed separately in this document, the RRKD and Wake Radiology proposals do not conform to all statutory review criteria and administrative rules and cannot be approved. Therefore, **DUHS** is the most effective alternative regarding this factor.

Historical Utilization

The following table illustrates historical utilization of each fixed MRI scanner owned by an applicant or related entity as provided in the 2023 SMFP representing FY2021 reported utilization.

Facility (Owner)	Fixed Scanners	Total Adjusted Procedures Performed during FFY2021	Adjusted Procedures per Scanner
Wake Radiology & Related Entities			
Rex Hospital – Main (UNC Health System)	2	11,373	5,687
Rex Hospital – UNC Rex Health Care of Cary (UNC Health System)	1	0	0
Wake Radiology MRI (WR Imaging, LLC)	1	3,867	3,867
Wake Radiology MRI (WR Imaging, LLC)	1	4,889	4,889
Wake Radiology / UNC Total	5	20,129	4,026
Duke University Health System			
Duke Radiology Holly Springs	1	1,938	1,938
Duke Raleigh Hospital	2	13,139	6,570
DUHS Total	3	15,077	5,026

Source: 2023 SMFP, Table 17E-1

Raleigh Radiology does not own any fixed MRI scanners. The average adjusted MRI procedures for the five existing fixed MRI scanners collectively owned by Wake Radiology and UNC is 4,026. The average adjusted MRI procedures for the three existing fixed MRI scanners owned by DUHS is 5,026. Therefore, **DUHS** is the most effective alternative regarding historical utilization.

Geographic Accessibility (Location within the Service Area)

The 2023 SMFP identifies the need for one fixed MRI scanner in Wake County. The following table identifies the location of the existing and approved fixed MRI scanners in Wake County.

Facility (Owner)	# of Fixed MRI Scanners	Hospital Based or Freestanding	Location
Raleigh Radiology – Cary (Alliance)^	1	Freestanding	Cary
Wake Radiology Diagnostic Imaging (Alliance)	1	Freestanding	Cary
WakeMed Cary Hospital (WakeMed)	1	Hospital	Cary
TOTAL FOR CARY*	3		
Wake Radiology – Garner (Alliance)^^	1	Freestanding	Garner
TOTAL FOR GARNER	1		
Duke Radiology Holly Springs	1	Freestanding	Holly Springs
Rex Hospital – UNC Rex Health Care of Cary*	1	Hospital	Holly Springs
TOTAL FOR HOLLY SPRINGS	2		
Duke Raleigh Hospital (Duke University Health System)	2	Hospital	Raleigh
Duke Imaging North Raleigh**	1	Freestanding	Raleigh
Rex Hospital – Main (UNC Health System)	2	Hospital	Raleigh
WakeMed (WakeMed)	2	Hospital	Raleigh
Raleigh Neurology Associates	1	Freestanding	Raleigh
Raleigh Neurology Imaging (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Blue Ridge (Alliance)	1	Freestanding	Raleigh
Raleigh Radiology – Cedarhurst	1	Freestanding	Raleigh
The Bone and Joint Surgery Center (Bone & Joint)	1	Freestanding	Raleigh
Wake Radiology (Wake Radiology)	1	Freestanding	Raleigh
Wake Radiology Raleigh MRI Center (Wake Radiology)	1	Freestanding	Raleigh
TOTAL FOR RALEIGH	14		

Source: 2023 SMFP, Table 17E-1

^ This MRI scanner is “permanently” installed. Pursuant to the need determination in the 2019 SMFP for one fixed MRI scanner in Wake County Raleigh Radiology, LLC applied for and was conditionally approved to develop a new fixed MRI scanner at Raleigh Radiology-Cary to replace the MRI scanner leased from Alliance. See Project ID# J-11825-19. This conditional approval is currently under appeal.

^^The single freestanding fixed MRI scanner shown to be located in Garner is the grandfathered fixed MRI scanner located at WR-Garner.

*Per Wake Radiology which formed a joint venture with UNC Rex HealthCare in late February 2019 the fixed MRI scanner at UNC Rex Healthcare of Cary is being relocated to the UNC REX Holly Springs Hospital upon completion of UNC REX Holly Springs Hospital in 2021.

**DUHS was approved to develop a fixed MRI scanner at an IDTF on the Duke Raleigh Hospital campus (Project ID # J-12073-21); however, that approval is under appeal.

Fixed MRI Scanners in Wake County (if each application was approved)

Municipality	July 1, 2021 Population Estimate	Fixed Scanners (Existing & Approved)	Average Population per Total Fixed Scanner
Cary	177,716	3	59,239
Garner	32,332	2*	16,166
Knightdale	19,674	1	19,674

Source: North Carolina Office of State Management and Budget. Population estimates from July 1, 2021.

*One of the two fixed MRI scanners shown to be located in Garner is the grandfathered fixed MRI scanner located at WR-Garner.

As described on application page 31, Wake Radiology currently offers fixed MRI services at its Cary location by contracting with Alliance Healthcare Services (Alliance) for use of a legacy MRI unit. Wake Radiology proposes to replace its existing leased fixed MRI scanner with a fixed MRI scanner that it owns and operates. Thus, the Wake Radiology proposal provides no benefit to Wake County residents from the perspective of immediate incremental geographic access. The Wake Radiology application is not an effective alternative from an access perspective.

The previous table indicates that there is a slightly larger average population per fixed MRI scanner in Knightdale compared to Garner, assuming that both applications were approved. However, DUHS would note the following:

- 1) One of the two fixed MRI scanners shown to be located in Garner is the grandfathered fixed MRI scanner located at WR-Garner, which is a legacy MRI scanner owned by Alliance and leased to WR-Garner. As Wake Radiology describes in its application, the vendor can decide against renewing the contract and the legacy MRI scanner can be re-homed at the end of the contract's term without CON approval. Therefore, there is no guarantee that the existing fixed MRI scanner located at WR-Garner will remain in Garner in the near future or long term. The ratio of population per fixed MRI scanner if only DUHS's proposed MRI scanner were located in Garner is 32,332, which is much larger than average population per fixed MRI scanner in Knightdale (19,674).
- 2) DUHS applied to acquire a mobile MRI scanner pursuant to the need determination in the 2023 SMFP, Project I.D. J-012378-23. If approved to develop a mobile MRI scanner, DUHS will develop a new mobile MRI host site at Duke Orthopaedics of Knightdale located at 162 Legacy Oaks Dr, Knightdale, NC 27545. The new mobile MRI host site will expand access to freestanding MRI services for the Knightdale area population.

As discussed separately in this document, the RRKD and Wake Radiology proposals do not conform to all statutory review criteria and administrative rules and cannot be approved. Therefore, **DUHS** is the most effective alternative regarding this factor.

Access By Service Area Residents

On page 344, the 2023 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2023 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1.” Based on that definition, the fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county. Wake County has more than one licensed acute care hospital. Therefore, for the purpose of this review, Wake County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

DUHS and RRKD project patient origin by zip code and Wake Radiology projects patient origin by county. Additionally, DUHS and RRKD each project “other” patients to include portions of Wake County and other North Carolina counties. Thus, a conclusive comparison of access by Wake County residents cannot be assessed. Therefore, the result of this analysis is inconclusive.

Competition (Patient Access to a New or Alternative Provider)

All the applicants and/or related entities provide MRI services in the service area of Wake County; therefore, none of the applicants would qualify as a new or alternative provider in the service area. However, the applications submitted by Wake Radiology and RRKD do not conform with all applicable statutory and regulatory review criteria. An application that does not conform to all applicable statutory and regulatory review criteria cannot be approved. Therefore, regarding this comparative factor, the application submitted by **DUHS** is the most effective alternative.

Access By Underserved Groups

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for all the applicants as a percentage of gross revenue, and per MRI scan, as shown below.

Applicant	Form F.2b	Form C.1b	Avg Charity Care per MRI	Form F.2b	% of Gross Revenue
	Total Charity Care	MRIs		Gross Revenue	
Duke	\$111,206	4,058	\$27	\$4,663,123	2.4%
Raleigh Radiology Knightdale	\$148,011	5,766	\$26	\$11,143,294	1.3%
Wake Radiology Cary	\$67,200	5,855	\$11	\$15,174,659	0.4%

Source: Section Q Form C and Form F.2b of the respective applications

DUHS proposes both the highest amount of charity care as a percentage of gross revenue and the highest amount of charity care per MRI scan. Therefore, with respect to charity care, **DUHS** is the more effective alternative.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review using gross Medicare dollars as a percentage of gross revenue.

Applicant	Form F.2b	Form C.1b	Avg Medicare Rev. per MRI	Form F.2b	% of Gross Revenue
	Total Medicare Revenue	MRIs		Gross Revenue	
Duke	\$1,631,549	4,058	\$402	\$4,663,123	35.0%
Raleigh Radiology Knightdale	\$3,131,266	5,766	\$543	\$11,143,294	28.1%
Wake Radiology Cary	\$6,693,637	5,855	\$1,143	\$15,174,659	44.1%

Source: Section Q Form F.2b of the respective applications

Two of the applicants, RRKD and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. As set forth above, charges and reimbursement rates also vary based on the specific procedure type. These differences in billing, which impact revenue (both gross and net) and expenses, do not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

However, it is possible to perform a conclusive analysis of Medicare MRI procedures as a percentage of total MRI procedures. Specifically, each applicant is required to complete Section L.3 which provides projected payor mix by payor source during the third full FY of operation following completion of the proposed project. One can apply each applicants’ payor mix projections to the number of projected MRI procedures during the third project year to assess access by Medicare patients, as shown in the following table.

	DUHS	RRKD	Wake Radiology
PY3 Unadjusted MRI Procedures	4,058	5,766	5,855
Medicare MRI Procedures as a % of Total MRI Procedures	35.7%	28.1%	35.1%
Medicare MRI Procedures	1,449	1,620	2,055

Source: Section L.3 and Section Q Form C.2b of the respective applications

DUHS projects the highest Medicare MRI procedures as a percentage of total MRI procedures. Wake Radiology projects the highest number of Medicare MRI procedures. However, Wake Radiology is simply replacing a leased fixed MRI scanner with an MRI scanner that will be owned by Wake Radiology. Thus, there is no incremental increase of access for Medicare patients. Additionally, the Wake Radiology application does not conform to the statutory review criteria and cannot be approved. Therefore, the **DUHS** application is the most effective alternative regarding access for Medicare patients.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants using gross Medicaid dollars as a percentage of gross revenue.

Applicant	Form F.2b	Form C.1b	Avg Medicaid Rev. per MRI	Form F.2b	% of Gross Revenue
	Total Medicaid Revenue	MRIs		Gross Revenue	
Duke	\$503,839	4,058	\$124	\$4,663,123	10.8%
Raleigh Radiology Knightdale	\$546,021	5,766	\$95	\$11,143,294	4.9%
Wake Radiology Cary	\$262,673	5,855	\$45	\$15,174,659	1.7%

Two of the applicants, RRKD and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. As set forth above, charges and reimbursement rates also vary based on the specific procedure type. These differences in billing, which impact revenue (both gross and net) and expenses, do not allow for a comparison between the applications. Thus, the result of this analysis is inconclusive.

However, it is possible to perform a conclusive analysis of Medicaid MRI procedures as a percentage of total MRI procedures. Specifically, each applicant is required to complete Section L.3 which provides projected payor mix by payor source during the third full FY of operation following completion of the proposed project. One can apply each applicants’ payor mix projections to the number of projected MRI procedures during the third project year to assess access by Medicaid patients, as shown in the following table.

	DUHS	RRKD	Wake Radiology
PY3 Unadjusted MRI Procedures	4,058	5,766	5,855
Medicaid MRI Procedures as a % of Total MRI Procedures	10.9%	4.9%	1.7%
Medicaid MRI Procedures	442	283	100

Source: Section L.3 and Section Q Form C.2b of the respective applications

DUHS projects the highest Medicare MRI procedures as a percentage of total MRI procedures and the highest number of Medicaid MRI procedures. Therefore, the **DUHS** application is the most effective alternative regarding access for Medicaid patients.

Projected Average Net Revenue per MRI Procedure

The following table shows the projected average net revenue per 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, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per MRI Procedure – 3rd Full FY

Applicant	Form C.1b	Form F.2b	Average Net Revenue per MRI
	MRIs	Net Revenue	
Duke	4,058	\$2,106,085	\$519
Raleigh Radiology Knightdale	5,766	\$1,997,073	\$346
Wake Radiology Cary	5,855	\$5,526,088	\$944

As shown in the table above, DUHS proposes the second lowest average net revenue per unadjusted MRI procedure in the third full fiscal year following project completion. However, two of the applicants, RPKD and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, do not allow for a comparison between the applications. In addition, the revenues for MRI procedures varies widely based on the specific payor as well as nature of the procedure, including use of contrast and the body part to be scanner. For example, the Medicare physician fee schedule for MRI procedures includes the following rates:¹

72148	A MRI lumbar spine w/o dye	\$207.64
72157	A MRI chest spine w/o & w/dye	\$348.83

Without information about the specific procedure mix projected by each applicant, the result of this analysis is inconclusive.

Projected Average Operating Expense per MRI Procedure

The following table shows the projected average operating expense per MRI procedure in the third full fiscal year following project completion for each project. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative with regard to this comparative factor to the extent it reflects a more cost-effective service, which could also result in lower costs to the patient or third-party payor.

¹ See <https://www.acr.org/-/media/ACR/Files/Advocacy/AIA/2023-FR-Impact-Table-70000-Codes.pdf>

Projected Average Operating Expense per MRI Procedure – 3rd Full FY

Applicant	Form C.1b	Form F.2b	Average Operating Expense per MRI
	MRIs	Operating Expense	
Duke	4,058	\$1,198,310	\$295
Raleigh Radiology Knightdale	5,766	\$1,755,364	\$304
Wake Radiology Cary	5,855	\$4,279,438	\$731

As shown in the table above, DUHS proposes the lowest average operating expense per unadjusted MRI procedure in the third full fiscal year following project completion. However, two of the applicants, RRKD and Wake Radiology, bill globally and include “professional fees” which cover professional interpretation of MRI studies by radiologists as an expense line in their pro formas. DUHS does not bill for “professional fees” nor does DUHS include an expense line in its pro formas for professional fees. These differences in billing, which impact revenue (both gross and net) and expenses, do not allow for a comparison between the applications. Similarly, the operating expense of a given procedure may vary based on use of contrast and other factors, such that the average operating expense reflects the specific procedure mix projected by each applicant. Thus, the result of this analysis is inconclusive.

Summary

Setting aside the issue of conformity, the following table lists the comparative factors and indicates whether each application was most effective, more effective, or less effective for each factor.

Comparative Factor	Duke	Raleigh Radiology Knightdale	Wake Radiology Cary
Scope of Services	Equally Effective	Equally Effective	Equally Effective
Historical Utilization	More Effective	Less Effective	Less Effective
Geographic Location in the Service Area	Equally Effective	Equally Effective	Less Effective
Access by Service Area Residents	Inconclusive	Inconclusive	Inconclusive
Competition (Access to a New MRI Provider)	Equally Effective	Equally Effective	Equally Effective
Projected Charity Care	More Effective	Less Effective	Less Effective
Projected Medicare	More Effective	Less Effective	Less Effective
Projected Medicaid	More Effective	Less Effective	Less Effective
Projected Avg Net Revenue per MRI Scan	Inconclusive	Inconclusive	Inconclusive
Projected Avg Operating Expense per MRI Scan	Inconclusive	Inconclusive	Inconclusive

As shown in the previous table, DUHS was determined to be a more effective alternative for the following factors:

- Historical Utilization
- Projected Charity Care
- Projected Medicare
- Projected Medicaid

Based on a comparative analysis presented above, the application submitted by **DUHS** is the more effective alternative proposed in this review for one additional fixed MRI scanner for Wake County and should be approved.

**COMMENTS SPECIFIC TO RALEIGH RADIOLOGY, LLC
PROJECT I.D. J-012393-23**

Comments Regarding Criterion (3) and 10A NCAC 14C.2703

In Step 7, RRKD identifies CY2023 as the baseline for projecting MRI procedures. However, CY2023 represents annualized RRKD MRI procedures based on only three months of data. The three-month annualized data represents only 25% of RRKD's annual utilization, which is insufficient to estimate annual utilization. Furthermore, the three-month annualized data results in a 3.15% growth rate over CY2022 MRI scans, which artificially inflates RRKD's baseline for projecting future utilization.

In Step 8, RRKD identifies CY2023 unadjusted MRI scans available to return to RRKD. However, CY2023 again represents annualized MRI procedures based on only three months of data. The three-month annualized data represents only 25% of the applicant's fiscal year, which is insufficient to estimate annual utilization. Therefore, RRKD's projected MRI utilization is questionable. RRKD failed to satisfy its burden of demonstrating utilization projections are based on reasonable and supported assumptions.

For these reasons, the RRKD application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the RRKD application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Criterion (13)

Section L.3 requires the applicant to project patients served by payor source and describe the assumptions used to project payor source. *See* RRKD application page 115. RRKD provides projections of MRI patients by payor source; however, RRKD failed to provide any information to describe the assumptions used to project payor source. Section L.1 provides historical payor mix information for *all* RRKD imaging services; therefore, the applicant failed to provide the historical payor mix specifically for its existing mobile MRI services. Based on the lack of any historical information for its existing MRI services and the absence of any assumptions used to project payor source, one cannot evaluate the reasonableness of RRKD's payor mix projections.

For these reasons, the RRKD application does not conform to Criterion (13). Additionally, based on the facts for which the RRKD application fails to conform to Criterion (13), it should also be found non-conforming to review criteria (1), (3), and (5).

Comments Regarding Comparative Analysis

As described previously in these comments, the RRKD application is comparatively inferior to the DUHS application for the following factors:

- Historical Utilization
- Projected Charity Care
- Projected Medicare
- Projected Medicaid

**COMMENTS SPECIFIC TO WR IMAGING, LLC & WAKE RADIOLOGY DIAGNOSTIC IMAGING, INC.
PROJECT I.D. J-012396-23**

General Comments

As described on application page 31, Wake Radiology currently offers fixed MRI services at its Cary location by contracting with Alliance Healthcare Services (Alliance) for use of a legacy MRI unit. Wake Radiology proposes to replace its existing leased fixed MRI scanner with a fixed MRI scanner that it owns and operates. Thus, the Wake Radiology proposal provides no benefit to Wake County residents from the perspective of geographic access. The Wake Radiology application is not an effective alternative from an access perspective.

Comments Regarding Criterion (3) and 10A NCAC 14C .2703

Wake Radiology describes need for the proposed project by identifying four factors, which include:

- The need for additional freestanding fixed MRI capacity in Wake County;
- The need for additional fixed MRI capacity within Wake Radiology;
- The need for fixed MRI capacity at Wake Radiology Cary; and
- The population growth in Wake County, including the growth in the population over age 65.

Three of the four factors that Wake Radiology identifies as the specific factors of need for the project focus on need for fixed MRI capacity; however, Wake Radiology's project results no net increase of fixed MRI capacity for Wake County or Wake Radiology but is simply a replacement of an existing scanner.

As a practical matter, patients utilizing Wake Radiology's existing fixed MRI services at the Cary facility will experience no change as a result of the proposed project. For example, the Wake Radiology project will not develop fixed MRI services in a new location, it will not establish a new freestanding, non-hospital based fixed MRI service, nor will it extend a portion of the cost savings from elimination of the lease contract to patients via lower out of pocket costs or expanded charity care. Taking these facts into account, the following statements in Wake Radiology's application are either false or misleading at best:

- Page 44: *"the addition of freestanding fixed MRI capacity within Wake Radiology will directly expand patients' access to the most subspecialized outpatient diagnostic imaging provider in the county"*
- Page 45: *"Patients also will benefit from a well-developed PACS (archived digital imaging) system which will reduce costs and improve quality by eliminating redundant scans and improving care coordination."*

Furthermore, upon review of Wake Radiology's methodology and assumptions for projecting fixed and mobile MRI utilization, DUHS acknowledges several oversights.

Wake Radiology Cary

Wake Radiology recently added a second day of mobile MRI access at its Panther Creek site. Based on the second day of mobile MRI access, Wake Radiology projects MRI utilization at Panther Creek to increase by 245 incremental mobile MRI scans during CY2023 and 490 incremental mobile MRI scans during CY2024. Wake Radiology acknowledges that some of the growth at the Panther Creek site could come from patients that would otherwise go to Wake Radiology Cary given the geographic proximity of that site (*i.e.*, they are both in Cary). See application pages 115-116.

On application page 116, Wake Radiology states, Wake Radiology conservatively projects that all of the incremental Panther Creek volume will shift from the fixed MRI at the Cary site. However, as reflected in the following table, Wake Radiology only subtracted volume equivalent to Panther Creek’s CY2023 incremental MRI volume from Wake Radiology and failed to account for the entire 490 incremental mobile MRI scans at Panther Creek during CY2024. Please see the following tables.

**Wake Radiology Cary Projected Shift
to Mobile MRI at Panther Creek in CY 2023 and CY 2024**

	CY22	CY23	CY24	CAGR
Total Adjusted Scans	5,414	5,690		5.1%
Shift to Second Mobile Day in CY 2023		-245		
Total Adjusted Scans Post First Shift		5,444	5,722	5.1%
Shift to Second Mobile Day in CY 2024			-245	
Total Adjusted Scans Post Second Shift			5,476	

Source: WR Imaging application page 116

**Wake Radiology Cary Projected Shift
to Mobile MRI at Panther Creek in CY 2023 and CY 2024
*Corrected to Reflect Shift of 490 MRI Scans During CY 2024***

	CY22	CY23	CY24	CAGR
Total Adjusted Scans	5,414	5,690		5.1%
Shift to Second Mobile Day in CY 2023		-245		
Total Adjusted Scans Post First Shift		5,444	5,722	5.1%
Shift to Second Mobile Day in CY 2024			-490	
Total Adjusted Scans Post Second Shift			5,232	

As shown in the previous table, adjusting Wake Radiology Cary’s MRI volume to reflect the shift of incremental volume at Panther Creek during CY2024 results in 244 fewer MRI procedures during CY2024 (5,476- 5,232 = 244).

The following table reflects the subsequent step of Wake Radiology’s methodology, which projects volume will increase by 5.1 percent annually after CY2024.

**Wake Radiology Cary Projected MRI Procedures
 Corrected to Reflect Shift of 490 MRI Scans During CY 2024**

		<i>PY1</i>	<i>PY2</i>	<i>PY3</i>	
	<i>CY24*</i>	<i>CY25</i>	<i>CY26</i>	<i>CY27</i>	<i>CAGR</i>
Total Adjusted Scans	5,232	5,499	5,779	6,074	5.1%

While this corrected volume exceeds the CON performance standard, the reduction in MRI procedures directly impacts Wake Radiology’s revenue projections and associated comparative factors.

Wake Radiology Mobile MRI Scanners

The following tables summarize historical utilization for Wake Radiology’s existing mobile MRI scanners which serve host sites in Wake County.

Wake Radiology Mobile #1#					
	<i>CY19</i>	<i>CY20</i>	<i>CY21</i>	<i>CY22</i>	<i>CAGR</i>
With Contrast	811	927	1,247	1,266	16.0%
Without Contrast	1,627	1,548	1,732	1,598	-0.6%
Total Outpatient Adjusted Scans	2,610	2,672	3,244	3,133	6.3%
		2.4%	21.4%	-3.4%	
Wake Radiology Mobile #2##					
	<i>CY19</i>	<i>CY20</i>	<i>CY21</i>	<i>CY22</i>	<i>CAGR</i>
With Contrast	759	852	902	915	6.4%
Without Contrast	962	1,199	1,430	1,413	13.7%
Total Outpatient Adjusted Scans	1,882	2,232	2,523	2,522	10.3%
		18.6%	13.0%	0.0%	

Source: WR Imaging application page 115

As shown in the table above, mobile MRI utilization decreased during CY2022 for Wake Radiology mobile MRI scanner #1 and was flat for Wake Radiology mobile MRI scanner #2. Wake Radiology failed to provide an explanation for the failure of growth during CY2022 and why utilization is now expected to increase by 2% during CY2023 and each following year through CY2027. While Wake Radiology may claim 2% simply reflects the population growth rate of Wake County, mobile MRI utilization declined during CY2022 despite ongoing population growth within Wake County. Therefore, the projected utilization of Wake Radiology’s mobile MRI utilization is questionable.

UNC Health Rex Hospital

The following table summarizes historical utilization for UNC Health Rex Hospital as presented in the Wake Radiology application.

UNC Health Rex Hospital					
	CY19	CY20	CY21	CY22	CAGR
With Contrast (Inpatient)	1,616	1,558	1,591	1,523	-2.0%
Without Contrast (Inpatient)	1,740	1,472	1,348	1,372	-7.6%
With Contrast (Outpatient)	2,406	1,906	2,477	2,489	1.1%
Without Contrast (Outpatient)	2,178	1,690	2,230	2,466	4.2%
Total Unadjusted Scans	7,940	6,626	7,646	7,850	4.2%
Total Adjusted Scans	11,686	9,982	11,058	11,208	-1.4%
Ratio of Unadjusted to Adjusted	1.47	1.51	1.45	1.43	-1.4%

Source: WR Imaging application page 113

As shown in the previous table, inpatient MRI utilization has decreased consistently during recent years. UNC Health Rex Hospital’s total adjusted scans are heavily influenced by the number of inpatient MRI procedures with and without contrast. As indicated by the decreasing ratio of adjusted to unadjusted MRI scans, much of weight on Rex fixed scanners is due to inpatient procedures which have been declining. Wake Radiology states its assumption to project static utilization at UNC Health Rex Hospital is conservative; however, Wake Radiology failed to provide any rationale to justify why UNC Health Rex Hospital’s inpatient MRI utilization will not continue to decrease. Therefore, the projected utilization of UNC Health Rex Hospital’s MRI utilization is questionable. Utilization of UNC Health Rex Hospital’s MRI scanners factors into the performance standards identified in 10A NCAC 14C.2703. Wake Radiology failed to satisfy its burden of demonstrating utilization projections are based on reasonable and supported assumptions.

For these reasons, the Wake Radiology application should be found non-conforming to Criterion (3) and 10A NCAC 14C.2703. Additionally, based on the facts for which the Wake Radiology application fails to conform to Criterion (3), it should also be found non-conforming to review criteria (1), (4), (5), (6), and (18a).

Comments Regarding Comparative Analysis

As described previously in these comments, the Wake Radiology application is comparatively inferior to the DUHS application for the following factors: Historical Utilization, Projected Charity Care, Projected Medicare, and Projected Medicaid.