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June 31, 2023

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Re: Comments on Competing Applications for a Certificate of Need for mobile MRI based on a statewide need; CON Project ID Numbers:

Project ID	Name
J-12393-23	Raleigh Radiology, LLC, One Fixed 1.5 T MRI in Knightdale
J-12395-23	Duke University Health System, Inc., One Fixed 1.5 T MRI in Garner
J-12396-23	WR Imaging, LLC, One Fixed 3T MRI in Cary

Dear Ms. Mitchell, Ms. Hale, and Ms. Saporito:

On behalf of Raleigh Radiology, LLC (“RRLLC”), Project ID J-12393-23, thank you for the opportunity to comment on the above referenced applications for a new fixed Magnetic Resonance Imaging scanner (“MRI”) in Wake County. We understand that your time is limited, so we have tried to focus comments on important issues in this review.

We believe that the applications submitted confirm and support the proposal from RRLLC as the most qualified to address the identified need.

We understand that the State’s Certificate of Need (“CON”) award for the proposed fixed MRI scanner must be based upon the statutory review criteria in G.S 131E-183 and that the Agency has discretion in choice of comparative factors when all applicants conform to the statutory review criteria.

In reviewing the applications, we know that the Agency will consider the extent to which each applicant meets all statutory review criteria. When comparing these applications, we ask that you weigh each application for sustainable, cost-effective, high-value, quality, multi-specialty MRI imaging services, and, recognize the void in MRI services in eastern Wake County and nearby communities.

Among the three, Raleigh Radiology, LLC proposes the best location for the next fixed MRI in Wake County. It also excels in other factors.

raleighrad.com | 5220 Greens Dairy Rd, Raleigh, NC 27616

Why Approve Raleigh Radiology

Choice in the Market

RRLLC proposes to acquire a fixed 1.5T MRI to replace a part-time mobile MRI at its existing Raleigh Radiology Knightdale (“RRKD”) practice. This diagnostic center opened three years ago, in June 2020, and demand for services escalated quickly. The site cannot meet current demand for MRI scans with the amount of time available on the mobile MRI that is leased from and operated by a third-party vendor. RRLLC is the only applicant that demonstrated that it is referring patients to other RRLLC locations because of capacity issues at the proposed site..

The 2023 SMFP need determination for a new fixed MRI identifies the service area as “Wake County.” The standard SMFP methodology is built on demand for MRI services in Wake County. As RRLLC clearly describes the eastern portion of Wake County—including Knightdale, Wendell, and Zebulon – as well as rural communities that border eastern Wake County -- depend on services in Wake County. This geography is a **fixed MRI service desert**. The only freestanding outpatient MRI in this part of Wake County is the part-time mobile unit at RRKD that is owned and operated by a third party. RRLLC does its best to accommodate patients locally, but the mobile has reached its limits.

As detailed in the RRLLC MRI application, when freestanding outpatient MRI services are unavailable locally, resident choices are not ideal—delay the scan, travel farther to another freestanding MRI, or use high-cost hospital-based MRI. Because the 2023 SMFP need determination permits only one award, it is important to consider which applicant proposes to reach the largest currently underserved population group, the best cost savings and proposes the highest patient value for the widest scope of services. The fixed freestanding MRI unit nearest to RRKD is *at least 45 minutes, 1.5 hours roundtrip*, from Knightdale, in central Raleigh at Raleigh Radiology Oberlin or Wake Radiology Merton Drive.

Industry Leader

RRLLC has demonstrated sustained commitment to and leadership in the imaging field for more than two decades. RRLLC was the first radiology practice in Wake County to introduce: 3D breast tomosynthesis mammography, Positron Emission Tomography, and high-field 1.5T open bore MRI. RRLLC took the lead in making MRI imaging affordable to patients by introducing a competitively **low-price fee schedule alongside a generous discount policy**. Matching actions with intent, RRLLC has developed strong relationships with Federally Qualified Health Centers, and free clinics that traditionally serve low-income persons, making specific commitments to accept referrals from these groups. It also focuses on affordable care for working families and individuals.

History of Quality

The radiologists who will interpret scans for this proposal, employees of Raleigh Radiology Associates, Inc. (“RRA”) includes 45+ board certified and specialized staff radiologists. These physicians are located in Wake County and available to consult in person and virtually with referring physicians via the “Radiologist Hotline” (see the section “Service Program Features” beginning on page 33 of the RRLLC application). RRKD operates as a radiologist office. As distinguished from the application that proposes an IDTF, specifically Duke University Health System, RRA radiologists are on site at RRKD today and will continue to be on site at RRKD. The physician’s presence means that patients have access to flexible

schedules for contrast studies. As one of its many quality features, RRKD application includes a budget for physicists to regularly review and calibrate imaging equipment owned by Raleigh Radiology. This quality standard would extend to any MRI equipment that Raleigh Radiology would own. As noted in the application, the proposal from RRKD will extend the features of Raleigh Radiology’s Breast Center of Excellence program, which is already functioning at RRKD.

Demonstrated Patient Demand and Cost Savings

The application from RRLLC is the only one that demonstrates cost savings compared to leased equipment alternatives. Others make that assertion, but only RRLLC demonstrates the savings. (Refer to Sections C.1 and N and Exhibit N.1 in the RRLLC application).

Comparative Review

The following discussion addresses key comparative points among the three applications.

Statutory Review Criteria Comparison

RRCH’s application conforms to all statutory review criteria. The remaining two applications failed to conform completely. Table 1 below summarizes conformity by criterion. For explanations of non-conformity, see detailed comments attached to this letter.

Table 1 – Comparison of Applicants’ Conformance to Statutory Criteria

Statutory Criterion	RRLLC	DUHS	WRLLC
1	C	NC	NC
3	C	NC	NC
3a	N/A	N/A	N/A
4	C	C	NC
5	C	NC	NC
6	C	C	NC
7	C	C	NC
8	C	C	C
9	C	C	C
12	C	C	NC
13	C	C	NC
14	C	C	C
18(a)	C	NC	NC
20	C	C	C
Performance Standard	C	NC	NC

Notes: “C” means conforming, “NC” means non-conforming

Competitive Metrics

RRLLC understands that the Agency has discretion in its competitive review of conforming CON applications. We urge the Agency to consider metrics that represent the spirit and intent of the 2023 SMFP and the CON Statute regarding value, quality, and accessibility. Table 4 summarizes our recommendations for a strong and reasonable comparison of the three applications. We have highlighted a few issues in the following paragraphs.

Competition

Competition improves access. Two applicants individually own almost one-fourth of the fixed MRI scanners located in Wake County. RRLLC is the only applicant that does not own or operate a Fixed MRI scanner in Wake County.

Table 2: Comparison of Fixed Wake County MRIs Owned / Operated by Applicants

Applicant	Fixed MRs	% Total	Proposed	New % Total
Raleigh Radiology, LLC	-	0.0%	1.0	4.8%
WR Imaging, LLC	5.0	25.0%	1.0	28.6%
Duke University Health System, Inc.	4.0	20.0%	1.0	23.8%
<i>Wake County</i>	<i>20.0</i>		<i>21.0</i>	

Source: Table 17E-1, 2023 SMFP

Access by Medically Underserved

In other decisions, the Agency has evaluated access by comparing Medicare and Medicaid patients with four metrics:

- Total gross revenue Medicare and Medicaid (dollars);
- Medicare and Medicaid as a percentage of gross revenue (percent);
- Total Medicare and Medicaid procedures per scanner (count per scanner owned); and,
- Total Medicare and Medicaid patients (count for proposed scanner).

In most reviews, the Agency treats Medicare and Medicaid beneficiaries as the marker of medically underserved patients. However, Criterion 13 reads:

“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 handicapped persons, 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.” [emphasis added]

While each beneficiary group listed in Criterion 13 has been medically underserved, the statute uses the words “such as.” A plain English interpretation of that phrase means those groups are examples, not a definitive list. As a result, comparing access by Medicare and Medicaid patients alone does not acknowledge the healthcare landscape in 2023. It ignores other medically underserved groups that may have greater access issues.

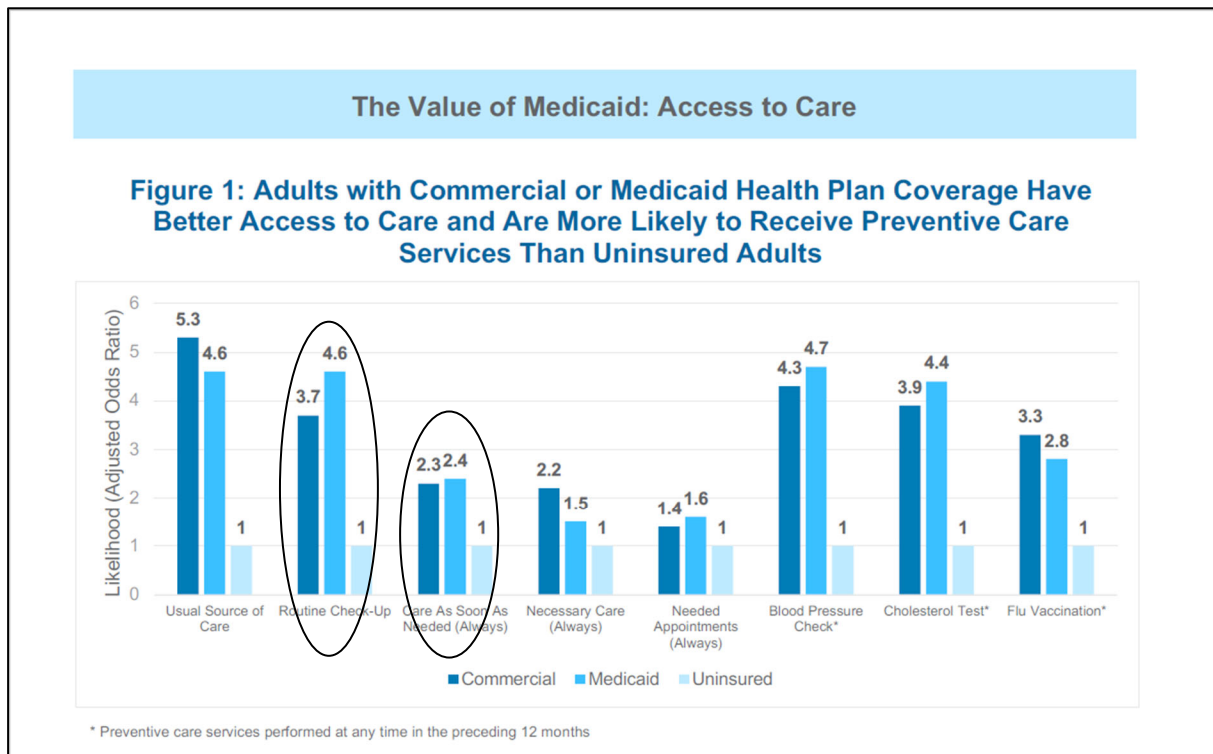
A report published by AHIP in April of 2018 “The Value of Medicaid”¹ compares patient access among Medicaid beneficiaries, commercial insurance users, and uninsured patients. It provides three key takeaways:

“Adults and children enrolled in a Medicaid health plan had significantly better access to care and preventive services than people with no health coverage.”

Overall, this analysis demonstrates a consistent pattern of strong, statistically significant relationships between insurance coverage— whether commercial or Medicaid—and access to care and preventive care services.

The findings from this study refute outdated, less rigorous studies that question the value of Medicaid, and add to the growing number of recent studies that demonstrate the value of having insurance coverage generally, and Medicaid more specifically.”

Data provided in this report shows that, in some instances, Medicaid beneficiaries have *better* access to care than commercially insured; but more importantly, uninsured is across the board the group with the greatest access challenge. See **Attachment I** for excerpts from the report.



¹ “The Value of Medicaid: Providing Access to Care and Preventive Health...” AHIP, www.ahip.org/resources/the-value-of-medicaid-providing-access-to-care-and-preventive-health-services. Accessed 27 July 2023.

As a result of changes in commercial insurance in recent years, most commercially insured patients are themselves the first dollar payor. They may classify as commercially insured, but the share paid by the insurance company is small. They are virtually uninsured.

Charges

Charges are important. Although Medicare and Medicaid fix their rates and pay most providers the same amount according to their class (hospital, physician office, IDTF), commercial insurers negotiate rates. Private and self-pay users of the services are then dependent on the applicant's charity policy when those negotiated rates or the provider's charges are beyond their means.

As demonstrated in **Attachment G** to these comments, commercial rates differ significantly among the three applicants in this batch. These details come from a search on Blue Cross Blue Shield's website and show that costs to commercial payors for the same type of MRI scan vary substantially among the applicants. Furthermore, according to Healthcare.gov, a Wake County Bronze plan for a 35-year-old is \$290.40 a month, has a deductible of \$8,800, and covers \$80 of the specialist physician charge. Others with lower deductibles cover only half of the specialist charge². Commercial payments affect subsequent year insurance rates for individuals and companies. They are important.

Projected Average Operating Expense per Weighted MRI Procedure

In other reviews, the Agency has compared projected average operating expense per MRI scan, noting that *"generally, the application projecting the lowest average operating expense per MRI scan 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."* Historically, the Agency has used this comparative metric when some applicants bill Globally, and others bill only the Technical fee. However, in a recent Decision at the ALJ level, Melissa Owens Lassiter Administrative Law Judge ruled that while revenue could not be compared, operating costs could be compared by removing the professional fees expense line item (see **Attachment F**, 21 DHR 04543). In the current batch, DUHS proposes to bill only a Technical fee; RRLLC and WakeRad propose to bill Globally. Table 3 below compares metrics for each application by removing the Professional fee component from expenses in Form F.3b.

² <https://www.healthcare.gov/see-plans/#/plan/results>

Table 3: Comparison of Technical Operating Costs per Weighted MRI Procedure, All Applicants, PY3

Metric	Raleigh Radiology, LLC	Wake Radiology, LLC	Duke University Health Systems, Inc.
a. Total Operating Costs	\$1,755,364	\$4,279,438	\$1,198,310
b. Less Professional Fees	\$(433,959)	\$(1,740,605)	-
c. Technical Operating Costs	\$1,321,405	\$2,538,833	\$1,198,310
d. Adjusted MRI Scans	6,130	6,356	4,411
e. Technical Cost per Procedure	\$215.56	\$399.44	\$271.66

Notes and Sources:

- a. *Forb F.3b, PY3*
- b. *Form F.3b, PY3, Professional Fees line item*
- c. *a – b*
- d. *Form C.2b, PY3*
- e. *c / d*

Table 3 demonstrates that RRLLC is the least costly and the most effective alternative regarding this important metric. Its technical cost per procedure, \$215.56, is \$56 less than DUHS and \$184 less than WakeRad.

Conclusion

We reviewed and rated all of the applications on need, access, and value metrics. For ease of presentation, the following Table 4 ranks applications Most to Least Effective as follows:

- 0. Equally Effective
- 1. Most Effective
- 2. More Effective
- 3. Least Effective

The table shows that **RRLLC is the applicant with the lowest score** and therefore the most effective alternative for a new fixed MRI in Wake County.

For detailed supporting scores for each metric chosen and rejected, please see [Attachment C](#).

Table 4: Summary Comparison of Applicants on Access, Quality, and Value Metrics

Metric	RRLC	WRLC	DUHS
Conformity to Statutory Review Criteria	1	3	3
Scope of Services (most types of scans performed)	0	0	0
Historical Utilization of the Facility (percent utilization)	2	1	3
Historical Utilization of the Facility (total scans)	2	1	3
Geographic Accessibility (closest to patients in need)	2	3	2
Competition (increased competition in service area)	1	3	3
Access by Service Area Residents (percentage of service area residents, PY3)	2	1	3
Access by Service Area Residents (number of service area residents, PY3)	2	1	3
Access by Medicare Patients (total Medicare dollars, gross revenue, PY3)	2	1	3
Access by Medicare Patients (Medicare as a percent of gross revenue, PY3)	3	1	2
Access by Medicare Patients (total Medicare procedures per scanner, PY3)	2	1	3
Access by Medicaid Patients (total dollars, gross revenue, PY3)	1	3	2
Access by Medicaid Patients (Medicaid patients as a percent of gross revenue, PY3)	2	3	1
Access by Medicaid Patients (total Medicaid procedures per scanner, PY3)	2	3	1
Projected Average Net Revenue per MRI Procedure, PY3	2	3	1
Projected Average Operating Expense per MRI Procedure, PY3	2	3	1
Total Score	28	31	34

Thank you for the time and attention you and your staff give to reviewing these important and detailed documents. Please do not hesitate to contact me should you have any questions.

Sincerely,



[Frank Manole \(Jul 28, 2023 10:44 EDT\)](#)

Frank Manole, COO
Raleigh Radiology, LLC

Attachment(s)

Attachments

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ATTACHMENT A

Competitive Review of – Duke University Health Services, Inc., J-12395-23

Overview

Duke University Health Services, Inc. (“DUHS”) proposes to acquire one new fixed Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determination for one new fixed MRI in Wake County. The application proposes a 1.5 Tesla (“1.5T”) MRI scanner to be installed at a diagnostic center under development in Garner (Project ID# J-12328-23. That project was conditionally approved May 5, 2023). At \$5.3 million, this is the most expensive of the three proposals,

This would be the fourth or fifth fixed MRI owned by the applicant (an approved MRI for North Raleigh is under appeal). The applicant proposes to organize it as an IDTF and lists charges on Form F.2 as Technical fees only.

As illustrated in the following discussion, the DUHS application is non-conforming with review criteria 1, 3, 5, 18a, and the Performance Standard in 10A NCAC 14C .2703(a).

CON Review Criteria

- 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, ambulatory surgery operating rooms, or home health offices that may be approved.**

Because the 2023 SMFP has a need determination for one new fixed MRI in Wake County, Policy GEN-3 “Basic Principles” applies. This policy reads,

“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.”

DUHS’s application **does not meet the requirements of this policy.**

- DUHS does not “document how its projected volumes incorporate these concepts in meeting the... needs of all residents in the proposed service area.” For details see discussion of Criterion 3 below.

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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

In the Methodology for Forms C.2a and C.2b, the application defines a catchment area that includes east and southeast Wake County zip codes, including Garner, Clayton, Knightdale, and Wendell. The service area excludes Zebulon (application pages 104 and 105). The application forecasts future demand from one point data, 9 months of FY2023. The application also notes on page 109 that DUHS MRI procedures declined in FY 2020 and FY 2021, as a result of the COVID 19 emergency.

Projections include both hospital based and IDTF facilities, leased and owned MRI scanners. It assumes two percent annual increases from the annualized estimate, based on forecast growth of Wake County population, indicating that the estimate is reasonable because the CAGR for DUHS procedures was throughout 8.1 percent. This is both optimistic and misleading. First, according to national demographer Claritas, Wake County is only expected to grow 1.37 percent annually between 2023 and 2028. Furthermore, zip codes in the DUHS catchment area are only expected to grow 1.52 percent in that same time frame. See Table 1 below. Finally, on page 104, Step 3, the application notes that DUHS existing sites have capacity constraints. Capacity constraints would make it impossible for all DUHS sites to achieve the forecast volumes. These growth projections are thus invalid because they rely upon compounding of procedures that DUHS cannot accommodate.

Table 1: Population Growth by Duke Garner Catchment Area Zip Codes and Wake County, 2023-2028

Area	CY23	CY24	CY25	CY26	CY27	CY28	CAGR	CY28 % Total
27520	99,494	101,166	102,865	104,594	106,351	108,138	1.68%	29.3%
27527	77,396	79,359	81,372	83,436	85,552	87,722	2.54%	23.8%
27529	114,178	115,825	117,496	119,191	120,910	122,654	1.44%	33.3%
27545	68,726	69,754	70,797	71,856	72,931	74,022	1.50%	20.1%
27591	52,682	53,533	54,398	55,277	56,170	57,078	1.62%	15.5%
27603	116,452	117,974	119,517	121,079	122,662	124,266	1.31%	33.7%
27610	154,822	156,494	158,184	159,892	161,619	163,364	1.08%	44.3%
Duke Garner Catchment	341,875	347,064	352,333	357,681	363,110	368,622	1.52%	100.0%
Wake County	1,181,640	1,197,877	1,214,337	1,231,023	1,247,939	1,265,087	1.37%	

Source: Claritas Pop-Facts Premier; accessed 07.17.23; 2023 and 2028 provided, all other years interpolated.

On page 104 and 106, the application clearly indicates that payers often prefer non-hospital-based services. Only two DUHS sites bill as IDTFs (see page 35). The others bill as hospital outpatient departments. Data in the methodology on page 109 show that procedures at these hospital sites have not returned to 2019 levels.

The application provides no explanation why patients from southeast Wake County received MRI procedures DUHS facilities in central and North Durham. Perhaps they work in Durham, or perhaps their MRI involved a specialist or other procedures available only at these facilities. The application provides no detail by zip code that would validate a trend of increasing MRI services by catchment area residents at these DUHS facilities.

This is important because the application then proposes to “shift” half of the projected procedures to the new Garner location. It provides no evidence to demonstrate that such a shift has occurred when the applicant opened other IDTFs. Three of those are owned by the provider.

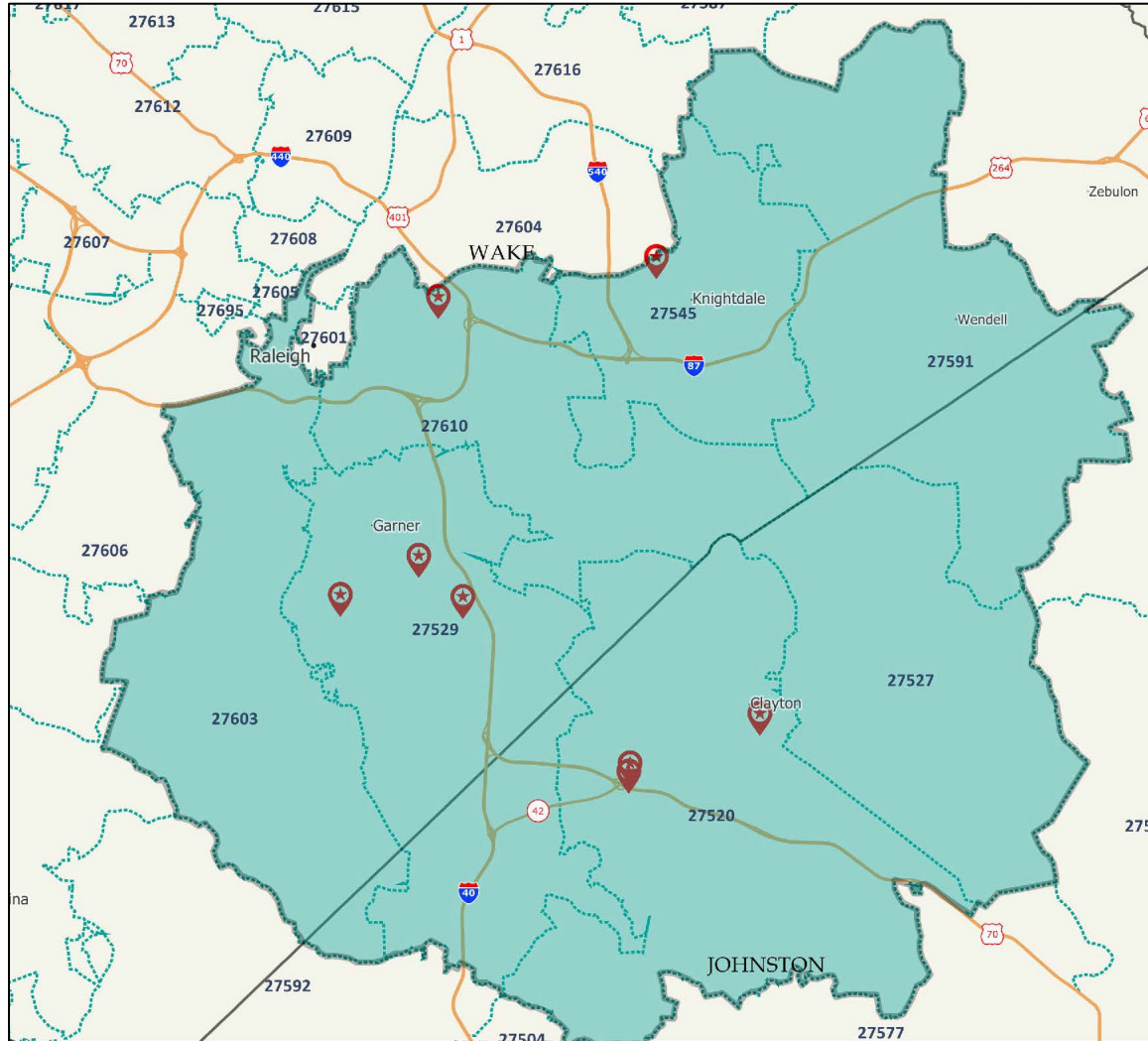
The first project year is FY 2026, four years after the baseline used in the forecasts. On page 60 the Applicant acknowledges presence of Wake Radiology MRI in Garner (27529) as the only fixed MRI in the proposed catchment area. However, DUHS does not acknowledge the eight other freestanding MRI service sites within its proposed catchment area, including EmergeOrtho, Cardinal Points Imaging, and Raleigh Radiology.

Table 2: Fixed Equivalent MRI Scanners in the DUHS Catchment Area

MR Type	Provider	Third-Party Owner / Operator	Address	City	Zip	FE MRI
Mobile	Raleigh Orthopaedic Clinic	N/A	1325 Timber Drive	Garner	27529	0.31
Freestanding Fixed	Wake Radiology MRI	N/A	300 Health Park Drive	Garner	27529	1.00
Mobile	WakeMed Garner Healthplex	Alliance HealthCare Services	400 US Highway 70 East	Garner	27529	0.06
Mobile	Raleigh Radiology - Knightdale	Alliance Healthcare Services, Inc.	1101 Great Falls Court	Knightdale	27545	0.48
Mobile	WakeMed-Raleigh Medical Park	Alliance HealthCare Services	23 Sunnybrook Road	Raleigh	27610	0.13
Mobile	Cardinal Points Imaging of the Carolinas Clayton	N/A	166 Springbrook Avenue	Clayton	27520	0.67
Mobile	EmergeOrtho Clayton (per website)	N/A	2196 NC Hwy 42 W	Clayton	27520	0.17
Mobile	Raleigh Radiology	Alliance HealthCare Services	11618 US 70 Business	Clayton	27520	0.12
Total FEMRIs in DUHS Catchment Area						2.94

Source: Table 17E-1 and Google searches

Figure 1: Fixed Equivalent MRI Scanners in the DUHS Catchment Area



It also is reasonable to include access points in Johnston County because a large number of residents in the catchment area – 53.1 percent – live in Johnston County. See calculation below.

a. 27520 Johnston County, Pop % of DUHS Catchment Area (Table 1)	29.3%
b. 27527 Johnston County, Pop % of DUHS Catchment Area (Table 1)	23.8%
c. Total Johnston County as % of DUHS Catchment Area (a + b)	53.1%

Source: see Table 1 above

Finally, at least six of the listed providers in Table 2 and Figure 1 are less costly to patients than IDTF services because IDTFs bill patients twice, the second bill from DUHS includes physician professional bills from Duke Physicians Network or the Duke Private Diagnostic Clinic. When price is the determining factor, people will choose those locations over the more costly DUHS hospital-based locations. Hence, the projected growth from residents of the catchment area at those hospital-based locations may not occur.

Patients have the final say in choice of location. The application provides no information about patient decisions. It suggests that DUHS is the sole broker of where patients will go for care and assumes that DUHS can shift patients. A recent ALJ Final Decision, 20 DHR 03986 notes the following:

“144. The Atrium Lake Norman Application did not explain why the patients going to other Atrium Health Facilities that offered higher levels of care than the proposed Atrium Lake Norman would choose to go to the new hospital. ‘They’re proposing to put an entirely new Atrium location with lower clinical services in that area where patients have already chosen other Atrium facilities... the applicant didn’t explain why suddenly these patients would go to this particular location,’ Faenza, Volume 2, page 407.”

The methodology (Step 6) assumes 15 percent in-migration because other DUHS Wake facilities have 15 percent in-migration. The application does not separate the specialist-based facilities from facilities similar to the proposed Garner facility that will be staffed by primary care providers in these initial years.

Together, these issues cast substantial doubt on the reasonableness of the application’s utilization forecast. With questionable utilization forecasts, the application should be found non-conforming to Criterion 3.

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.

See discussion of need methodology in Criterion 3 above. The application provides insufficient information to support procedure volumes that drive the financial forecasts.

Moreover, payor mix information is incomplete. Section L.3 includes a few assumptions indicating that, with the exception of ultrasound, payor mix is based on DUHS patient age and demographics.

Payor mix assumptions refer back to Section L, which indicate that payor mix for the proposed Garner facility is based on “baseline data for DUHS outpatient MRI patients for P1-9 FY2023 used for the volume projections in Section Q.”

As noted in the discussion of Criterion 3 above, DUHS payor mix is dominated by three major inpatient facilities, none of which are located in Garner. The assumptions on Medicare are difficult to follow quantitatively. They refer to DUHS finance “updates during the annual budget preparation.” The reader cannot determine how many “shifts” from Commercial Managed Care to Medicare occur. In fact, the application simply notes that “the aging assumption would have a negligible effect on projected mammography and ultrasound patients by payor type at this facility....”

The application says that the applicant will open the proposed MRI in an IDTF. However, DUHS filed at least one CON application indicating intent to place an inpatient facility on that Garner campus. Will the applicant keep the proposed fixed MRI in an IDTF arrangement, or is the ultimate goal to make this a hospital MRI?

Finally, DUHS proposes to do contrast MRI scans at same percentage as its hospitals, see p111. Contrast scans require on-site presence of a physician, Advanced Practice Provider, or a registered nurse following a “sign-driven treatment algorithm” than can manage contrast reactions (see **Attachment G**). DUHS’s application is silent on how this freestanding IDTF will provide that essential element of contrast MRI services. The proposed staffing on Form H includes **none** of these individuals. Without this essential staff, 43 percent of the proposed scans will not meet CMS billing criteria or ACR accreditation requirement, see page 108.

For these reasons the applicant should be non-conforming to Criterion 5.

- 18 a. 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 the service for which competition will not have a favorable impact.**

Competition

The 2023 SMFP reports 20 operational fixed MRIs in Wake County -- 12 freestanding and eight hospital-based. Of these four, approximately 20 percent are owned / operated by DUHS, giving DUHS the second highest percentage ownership of all Wake County fixed MRI scanners. See Table 4 below for details.

Table 3: Comparison of Fixed Wake County MRIs Owned / Operated by Applicants

Applicant	Fixed MRs	% Total	Proposed	New % Total
Raleigh Radiology, LLC	-	0.0%	1.0	4.8%
WR Imaging, LLC	5.0	25.0%	1.0	28.6%
Duke University Health System, Inc.	4.0	20.0%	1.0	23.8%
<i>Wake County</i>	<i>20.0</i>		<i>21.0</i>	

Source: Table 17E-1, 2023 SMFP

Addition of the proposed scanner at Duke Garner **will not introduce a new competitor** in Wake County.

CON Rules**10A NCAC 14C .2703(a) Performance Standard**

As noted in the discussion of Criterion 3, utilization forecasts are substantially overstated. The application only achieves the required performance standards if these overstated forecasts are supportable. They are not. The application should be found non-conforming with the performance standard.

ATTACHMENT B

Competitive Review of WR Imaging, LLC / Project ID #J-12396-23

Overview

WR Imaging, LLC (“WakeRad”) applied to acquire one new fixed Magnetic Resonance Imaging scanner (“MRI”) at its location, Wake Radiology Cary (“WRCary”) in response to the 2023 SMFP need determinations for one new fixed MRI scanner in Wake County.

The application proposes to acquire a Siemens MAGNETOM Vida 3.0 Tesla (“3.0T”) MRI scanner. The proposed scanner will replace its existing legacy installed MRI scanner owned and operated by Alliance Healthcare Services (“Alliance”).

As illustrated in the following discussion, the WakeRad application is non-conforming with statutory review criteria 1, 3, 4, 5, 6, 7, 12, 13, 18a, and the Performance Standard in 10A NCAC 14C .2703(a).

CON Review Criteria

- 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, ambulatory surgery operating rooms, or home health offices that may be approved.**

Because the 2023 SMFP has a need determination for one new fixed MRI in Wake County, Policy GEN-3 “Basic Principles” applies. This policy reads,

“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.”

WakeRad’s application **does not meet the requirements of this policy.**

- First, WakeRad does not demonstrate that it has “...plans for providing access to services for patients with limited financial resources.” As detailed in Criterion 13a below, self-pay and commercially insured patients with high-deductible health plans comprise the most at-risk group of patients with limited resources. WakeRad has the highest net revenue per scan among all applicants (see [Attachment C](#)), and its financial policy in Exhibit B.20-2 (p20) contains no indication that the Applicant provides discounts to qualified patients – like those with limited incomes, no insurance, or high out of pocket costs.

- Second, WakeRad does not “document how its projected volumes incorporate these concepts in meeting the... needs of all residents in the proposed service area.” Criteria 3 and 4 below detail how the WakeRad proposal will **net less than 10 percent** of the calculated deficit of scans in Wake County by its third year of operation. Additionally, the Applicant proposes a 3T scanner with specialized cardiac capabilities, but failed to demonstrate why this extra and expensive technology is needed by the population it proposes to serve.
- Finally, WakeRad does not demonstrate the “availability of capacity to provide these services.” Comments regarding Criterion 7 below provide more detail. The application indicates that the proposed equipment is intended to serve cardiac patients. However, WakeRad provides no indication that it has the necessary physician support – either in referrals or interpretation of images – to justify or provide cardiac MRI scans.

According to Criterion 1, “[t]he proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan,.” The Applicant proposes to replace an existing fixed MRI that it leases from a third-party vendor. The 2023 State Medical Facilities Plan constitutes a policy and need determination document. Hence, the Applicant must meet all policies and requirements set forth in Chapter 17E, Technology and Equipment, Magnetic Resonance Imaging Scanners. Step 9 of the MRI methodology in this chapter (p332) reads:

“9. A facility that offers MRI services on a full-time basis pursuant to a service agreement with an MRI provider is not precluded from applying for a need determination to replace the existing contracted service with a fixed MRI scanner under the applicant’s ownership and control. It is consistent with the purposes of the CON law and the SMFP for a facility to acquire and operate an MRI scanner to replace such a contracted service, if the acquisition and operation of the facility’s own MRI scanner will allow the facility to reduce the cost of providing the MRI service at that facility.” [emphasis added]

Apart from a single statement that “[d]eveloping the proposed fixed MRI scanner at WRCary will ultimately reduce the fixed expenses associated with offering fixed MRI services,” (p92), WakeRad fails to demonstrate that replacement of the existing contracted service with an expensive 3T MRI will reduce the cost of providing MRI services at the Cary facility. WakeRad provides no information that would allow the Agency to verify that this Applicant meets this SMFP requirement.

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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.**

Demonstration of Need

Per the Criterion, applicants are required to “identify the population” to be served and “demonstrate the need this population has for the services proposed.” WakeRad fails on both accounts.

In Sections C.2 and C.3 the application identified patient origin from four specific counties, Wake, Harnett, Lee, Durham, and other counties. The application has little discussion of population need. Pages 49-53 mention population growth and aging in Wake County. None of the other counties are mentioned.

This project is in response to a need determination in the 2023 SMFP. This means that the standard methodology determined that the number of MRI scanners existing in Wake County will not be sufficient to meet the projected number of MRI scans needed in 2027. This methodology calculates a general need for all MRI scans; other than the inpatient and complex weights, the 2023 SMFP makes no exceptions or adjustments for specialized types of clinical scans. Because this Applicant proposes a specialized MRI scanner, the Applicant has the burden of proof that that specialized equipment is needed by the population it proposes to serve. In the Scope in Section C, the application indicates that the 3T equipment is needed to serve “brain and spine and orthopedic patients.”

A 3T scanner *can* do standard diagnostic imaging, but its feature is the specialized software options that allow radiologists to capture better images of hard-to-scan areas. WakeRad explains on page 32 that, “3T scans... are especially helpful when a **more sensitive diagnostic tool is needed**” [emphasis added].

According to the vendor quote, the only software that WakeRad proposes for this equipment that is **unique to a 3T** magnet, is “Advance Cardiac PSIR #Vi” (Exhibit C.1-2, page 26). This suggests that WakeRad is planning to target cardiac patients. However, at no point in its application does WakeRad identify this population, nor does the application demonstrate that cardiac patients need additional access to a specialized cardiac MRI scanner at WRCary. This equipment adds to the capital cost.

In Section C.4, WakeRad demonstrates only that it needs additional generic MRI capacity at WRCary to accommodate the ongoing “organic growth” that occurred over that last few years (p43). The application provides data to show that subsequent to formation of the Wake Radiology UNC Health Rex joint venture, MRI utilization at WakeRad locations increased. It asserts that the increase is due to a shift of patients away from hospital settings to freestanding outpatient settings as appropriate. The application mentions substantial numbers of subspecialist radiologists at WakeRad, but it does not mention cardiac MRI specialists.






WakeRad's application goes on to demonstrate the substantial growth and aging of the general population in Wake County, and how that growth is affecting adjacent counties. These statements lead the reviewer to believe that access to an MRI scanner with **broad capabilities** is important. It implies that any specialized software is excessive and unnecessary to meet the needs of the identified population to be served.

Furthermore, four of the 20 existing and operational fixed scanners located in Wake County – 20 percent – are *already* 3T scanners.¹ If WakeRad were approved, 25 percent (5 / 20 = 0.25) of fixed MRI inventory located in and owned by county providers would be 3T. This is an important distinction, Akumin, formerly Alliance Healthcare, owns legacy rights to MRI scanners, but their location is not restricted, and the scanners can be moved when the contracts end. WakeRad's application makes general reference to capabilities of 3T technology but fails to specifically demonstrate that the proposed population to be served needs 25 percent of the fixed MRI inventory in Wake County to be 3 Tesla MRI equipment that has specialized capability for cardiac MRI scans.

The 25 percent calculation excludes the 2019 and 2021 Wake County fixed MRIs which are both under appeal. Either or both of them *could* be developed as 3T scanners. One, specifically the Raleigh Radiology Cary decision, is for 3T equipment. Assuming the Courts continue to agree with the Agency, that scanner alone would bring the 3T inventory to 24 percent (5 of 21). In that case, the proposed WakeRad equipment would bring the county inventory to 6 of 22 or 27 percent of the inventory.

Forecasts in the methodology for WakeRad in Section Q are based on MRI procedures on 1.5 tesla equipment. Forecasts are not adjusted for limitations of 3T technology. In fact, the CAGR used in the forecast is itself artificial. It starts with the low COVID year, FY 2019, and ends with the recovery year FY 2022. Closer examination of the data shows that procedures are not improving as aggressively. CAGR calculations use only the first and last numbers in a sequence. The Percent Annual Change row and the Trend Column both show slower growth in procedures between 2021 and 2022. The following analyzes data from page 113 for the Cary location.

Table 1: Analysis of MRI Scans WakeRad Cary Location

WRCary	CY19	CY20	CY21	CY22	CAGR	Trend
With Contrast	1,469	1,762	2,037	2,013	11.1%	
Without Contrast	2,267	2,272	2,855	2,974	9.5%	
Total Outpatient Scans	3,736	4,034	4,892	4,987	10.1%	
Percent Annual Change		8.0%	21.3%	1.9%		
Total Outpatient Adjusted Scans	4,048	4,408	5,324	5,414	10.2%	

Source: page 113, WakeRad application

¹ This includes three freestanding, Cardinal Points Imaging of the Carolinas, The Bone and Joint Surgery Clinic, and WakeRad Merton Drive, and one hospital based at Duke Raleigh Hospital.

The need methodology divides the inflated CAGR in half to forecast 5.1 percent compound annual growth in demand at Cary. As illustrated in the table above, the forecast for demand is not reasonable. Moreover, the forecast makes no adjustment for scans that cannot be done on a 3T.

Similarly, forecasts of growth for other WakeRad sites on page 114 over-project need. They generously rounded up population growth in Wake County from actual 1.6 percent Compound Annual Growth Rate to 2.0 percent.

Table 2: Wake County Population Estimates NCOSBM

2023	2027	CAGR
1,189,705	1,288,980	1.6%

Source: NCOSBM Population Estimates

Because of questionable forecasts of the need of the population for the number of procedures forecast, the application by WakeRad should be found non-conforming to Criterion 3.

- 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.**

Alternatives

WakeRad failed to demonstrate that its proposal is the least costly or most effective alternative.

Increased Volume

WakeRad claims that the “proposed project to develop a fixed MRI scanner at its Cary office is the most effective alternative to meet the need for additional fixed MRI capacity in Wake County” (page 46). The WakeRad application also acknowledges that, according to the 2023 SMFP, Wake County scanners will have a deficit of 9,512 scans by planning year 2027². It is, of course, unreasonable to assume that one new MRI scanner could absorb the entire scan deficit. However, the WakeRad application will result in only 942 net new scans in Wake County by its third operating year ($6,356 - 5,414 = 942$)³.

WakeRad asserts on page 41 that it is the busiest provider of freestanding outpatient MRI scans in Wake County. But this is misleading. When considered individually, WakeRad scanners are not even in the top five busiest scanners in Wake County (see Table 3 below).

² The 2023 SMFP failed to determine what planning year Table 17E-2 represents. For ease of calculation, the Commenter assumes it to be the same year of WakeRad’s third year of operation, 2027.

³ Total estimated weighted scans 2027, Form C.2b, page 111 – Total reported weighted scans 2022, Form C.2a, page 110

Table 3: Comparison of Weighted Scans by Wake County Freestanding Fixed MRI Location

Provider	Owner/Operator	Tesla	# Fixed Scanner	FY21 Scans	FY21 Adjusted Scans
Raleigh Radiology-Blue Ridge	Alliance Healthcare Services	1.5T	1	6,715	7,146
Raleigh Radiology - Cary	Alliance Healthcare Services	1.5T	1	6,658	7,106
Cardinal Points Imaging of the Carolinas - Midtown	Pinnacle Health Services	3T	1	5,435	5,912
Raleigh Neurology Imaging, PLLC	Alliance Healthcare Services	1.5T	1	5,109	5,586
Raleigh Neurology Associates, P.A.	Raleigh Neurology Associates, PA	1.5T	1	4,829	5,298
Wake Radiology - Cary	Alliance Healthcare Services	1.5T	1	4,667	5,072
Wake Radiology - Merton Drive	WakeRad Imaging, LLC	1.5T	1	4,342	4,889
Wake Radiology - Garner	Alliance Healthcare Services	1.5T	1	3,794	4,136
Wake Radiology - Merton Drive	WakeRad Imaging, LLC	3T	1	3,478	3,867
The Bone and Joint Surgery Clinic	The Bone and Joint Surgery Clinic	3T	1	2,208	2,208
Duke Imaging Holly Springs	Duke University Health Systems	1.5T	1	1,763	1,938
2019 Need Determination (under appeal)			1	-	-
2021 Need Determination (under appeal)			1	-	-

Source: Table 17E-1, 2023 SMFP, and 2023 Equipment Registry Inventory Forms

For reference, both Raleigh Radiology and WakeRad have installed legacy Alliance owned and operated MRI scanners in Cary. Raleigh Radiology Cary performed **2,034 more weighted scans** than WRCary in the same time period with similar equipment and operational structure. This further illustrates the misleading nature of statements in Section C. Indeed, patients are seeking less costly MRI locations. However, as illustrated in the comparative table in the Cover Letter to these comments, WakeRad is not the least costly setting.

Even comparing the top five “freestanding systems,” WakeRad averages substantially fewer scans per scanner than other Wake County providers.

Table 4: Comparison of Weighted Scans per Wake County “Freestanding System”

Freestanding System	# Fixed Scanners	FY21 Adjusted Scans	Adjusted Scans / Scanner
Raleigh Radiology	2	14,252	7,126
Cardinal Points Imaging of the Carolinas	1	5,912	5,912
Raleigh Neurology Imaging, PLLC	1	5,586	5,586
Raleigh Neurology Associates, P.A.	1	5,298	5,298
Wake Radiology	4	17,964	4,491

WakeRad provides an inadequate answer to the obvious question about the proposed new scanner: why the existing legacy installed scanner cannot provide the proposed additional 942 weighted scans – only 18 additional MRI scans per week – nor why an equipment expenditure of \$2.6 million is needed to effectively achieve the increase.

Better Use of Resources

As explained in Criterion 1 above, WakeRad does not provide any evidence to demonstrate that it can terminate the Alliance contract and replace it at WRCary. Furthermore, WakeRad claims that its own “organic growth” is the basis for increased utilization across its network of imaging centers (pp41-44), suggesting that it needs more capacity.

However, WakeRad application does not discuss working with Alliance to continue service as a mobile unit at its other Wake County imaging centers. That option would provide more capacity to absorb and / or redistribute its own increasing volume (see pp41-44). This alternative would not only ensure a net new MRI scanner in Wake County, but also provide opportunity to serve more than 942 unmet Wake County scans. The application provides no information to show the additional scans, if any, the 3T would attract.

Because it does not demonstrate that its proposal is the least costly or most effective alternative, WakeRad should be found non-conforming to Criterion 4.

- 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.**

As discussed in Criterion 3 above, forecasts of procedures for the WRCary location are substantially overstated and unsupported. Thus, financial projections are not based on reasonable costs and charges.

The application has insufficient information to demonstrate that the cost of the proposed 3T MRI will be less than the current vendor arrangement.

Costs to provide the additional specialty cardiologists to assist with cardiac MRI procedures are not included.

Capital costs do not mention a ferromagnet scanner, which is now a patient safety requirement of FGI Guidelines for MRI. North Carolina Construction Section has adopted FGI Guidelines as the state standard.

Capital costs do not include the costs for physicists and calibration of the scanner.

The financing letter from First Citizens Bank has very little tolerance for error. It is only \$5,000 more than the capital costs identified on Form F.1a.

For these reasons, the WakeRad application should be found non-conforming to Criterion 5.

6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

WakeRad acknowledges that the need determination set forth in the 2023 SMFP is enough support to justify a new fixed MRI in Wake County and as a result its proposal will not result in unnecessary duplication of services. However, this is misleading.

As detailed in Criteria 3 and 4, WakeRad is proposing what will become the sixth, or possibly the seventh, 3T MRI scanner in Wake County. While the proposed equipment is likely capable of performing standard scans, WakeRad proposes that the increased cost of the 3T is worthwhile because of the specialized services it can provide. However, WakeRad already operates a 3T scanner at Merton Drive. The application has no discussion of the impact of changing from 1.5T to 3T.

In the discussion of duplication, the application asserts that “demand for freestanding MRI services in Wake County is growing quickly, especially the high-quality, sub-specialized MRI services offered at Wake Radiology facilities.” However, this assertion is not supported by data in the methodology table on page 113. That table shows that demand stalled in FY 2022 and the application provides no information for FY2023.

The application provides no quantitative data about the need for another 3T scanner in the WakeRad or Wake County inventory.

For these reasons, the application should be found non-conforming to Criterion 6.

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.

As explained in Criterion 3, WakeRad proposes the Advance Cardiac PSIR #Vi software as part of its 3T scanner. It appears that this is the only feature unique to a 3T that the Applicant proposes. The vendor quote includes no neurology, prostate or orthopedic features.

The 3T cardiology feature is specifically for conducting MRI scans on the heart. Capturing an accurate MRI image requires that patients be perfectly still. For instance, if a patient needs an MRI of their lungs, they must hold their breath for a period of time to ensure image clarity. Unfortunately, only the rare human can control movement of the heart. It beats autonomically, without conscious control. As a result, cardiac MRI requires highly specialized radiologists to both perform and read the scans. Please see the excerpt from ACR's Practice Parameters regarding cardiac MRI in [Attachment H](#).

WakeRad provides no information about relationships with or employment of physicians with the specialized training to use the cardiology feature. Review of the application, exhibits, and the WakeRad website show the following:

- Page 44 of its application reads, "Wake Radiology employs fellowship trained physicians from a variety of sub-specialties including breast imaging, neuroradiology, pediatric radiology, full body imaging, vascular and interventional radiology, and musculoskeletal radiology, among others." Cardiology is not listed.
- Exhibit I.2 includes **no letters of support** or referral from cardiologists or physicians that specialize in cardiac MRI radiology.
- WakeRad's website does not list cardiac imaging as an available sub-specialty.⁴

Because it did not demonstrate that it can provide the necessary health manpower required for operation of the 3T scanner, the application by WakeRad should be found non-conforming to Criterion 7.

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.

Because WakeRad did not demonstrate that costs associated with replacing its Alliance contract are the most reasonable alternative, it should be found non-conforming to Criterion 12. Please see Criteria 1 and 4 above for detail.

⁴ <https://www.wakerad.com/sub-specialties/>

Page 91, question 3.b answer indicates that the annual cost to contract for the Alliance Scanner at WRCary is \$1.1 M. Form F.2a on page 127 indicates that the Operating Cost for WRCary MRI is \$3.6 million. Form F.2b shows that the operating costs for the proposed new MRI in the first full year are \$3.8 million, which is more than the cost of the Alliance contract.

Capital costs include no contingency and do not include the required Ferromagnetic scanner. The contract does not explain how the location will sustain services during installation.

For these reasons, the application does not 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.

- 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 handicapped persons, 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;**

This application proposes a high percentage of services to commercially insured patients. However, the value associated with serving this group is cancelled by the high charges associated with this project. Please see section "Access by Medically Underserved" in the cover letter as well as [Attachment I](#).

In Section L, question 3.b, the application indicates that Charity care is not a patient class. The financial policy in Exhibit B.20-2 indicates that this Applicant does not offer charity care to anyone. Financial assumptions for Form F.2 on page 131 indicate that charity is the difference between charge and collections for self-pay patients. This would be consistent with bad debt. The bad debt assumption is bad debt percentage of total gross revenue. It appears that the financials double count the charity deduction.

- (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 physician.**

Again, the vendor quote in Exhibit C.2-1 suggests that this scanner will have some focus on cardiac patients. However, the Applicant fails to indicate who will refer such scans. See Exhibit I.2 which includes no letters of referral or support from cardiology groups.

- 18 a. 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 the service for which competition will not have a favorable impact.**

Competition

The 2023 SMFP reports 20 operational fixed MRIs in Wake County -- 12 freestanding and eight hospital-based. The Applicant, a joint venture between UNC Rex and WakeRad owns / operates five, or 28.6 percent, of all Wake County fixed MRI scanners. This is substantially more than any other provider. See Table 5 below.

Table 5: Number of Fixed Wake County MRIs Owned by Applicant

Applicant	Fixed MRs	% Total	Proposed	New % Total
Raleigh Radiology, LLC	-	0.0%	1.0	4.8%
WR Imaging, LLC	5.0	25.0%	1.0	28.6%
Duke University Health System, Inc.	4.0	20.0%	1.0	23.8%
<i>Wake County</i>	<i>20.0</i>		<i>21.0</i>	

Source: Table 17E-1, 2023 SMFP

Even if the courts finally agree with the Agency regarding Raleigh Radiology Cary 2019 MRI CON application, Raleigh Radiology will still have the lowest share of existing MRI units.

As the dominant provider, to increase competition, this Applicant would have to provide a lower charge – it does not; or a service not available – it does not, or enhanced services to an underserved group – its financial policy does not include charity care.

Replacement of the existing legacy scanner at WRCary **will not increase competition** in Wake County. It will, however, allow a higher-cost provider to maintain its dominant position in number of MRI scanners owned and operated in Wake County.

CON Rules**10A NCAC 14C .2703(a) Performance Standard**

As noted in the discussion of Criterion 3, utilization forecasts are substantially overstated. The application only achieves the required performance standards with these overstated forecasts. The application should be found non-conforming with the performance standard.

ATTACHMENT C

COMPARATIVE METRICS

Raw Data by Comparative Factor

Comparative Factor	Data is Best	RRLC	WRLLC	DUHS
Conformity to Statutory Review Criteria	Yes	Yes	No	No
Scope of Services (most types of scans performed)	Highest	Same	Same	Same
Historical Utilization of the Facility (percent utilization)	Highest	64%	108%	0%
Historical Utilization of the Facility (total scans)	Highest	3,175.0	5,414.0	0.0
Geographic Accessibility (closest to patients in need)	Yes	Yes	No	Yes
Competition (increased competition in service area)	Yes	Yes	No	No
Access by Service Area Residents (percentage of service area residents, PY3)	Highest	76.6%	86.2%	62.6%
Access by Service Area Residents (number of service area residents, PY3)	Highest	3,559	4,298	2,534
Access by Medicare Patients (total Medicare dollars, gross revenue, PY3)	Highest	\$3,131,266.00	\$,693,637.00	\$1,631,549.00
Access by Medicare Patients (Medicare as a percent of gross revenue, PY3)	Highest	28.1%	44.1%	35.0%
Access by Medicare Patients (total Medicare procedures per scanner, PY3)	Highest	1,620	2,583	1,415
Access by Medicaid Patients (total dollars, gross revenue, PY3)	Highest	\$546,021.00	\$262,673.00	\$503,839.00
Access by Medicaid Patients (Medicaid patients as a percent of gross revenue, PY3)	Highest	4.9%	1.7%	10.8%
Access by Medicaid Patients (total Medicaid procedures per scanner, PY3)	Highest	283	101	437
Projected Average Net Revenue per MRI Procedure, PY3	Lowest	\$1,932.59	\$2,591.74	\$1,153.10
Projected Average Operating Expense per MRI Procedure, PY3	Lowest	\$304.43	\$730.90	\$296.32

ATTACHMENT C

Raw Data Sources

Comparative Factor	RRLLC	WRLLC	DUHS
Conformity to Statutory Review Criteria	--	See Attachment B	See Attachment A
Scope of Services (most types of scans performed)	Section C.1	Section C.1	Section C.1
Historical Utilization of the Facility (percent utilization)	Form C.2a, Last Full FY	Form C.2a, Last Full FY	N / A
Historical Utilization of the Facility (total scans)	Form C.2a, Last Full FY	Form C.2a, Last Full FY	N / A
Geographic Accessibility (closest to patients in need)	Section C.4 and Methodology	Section C.4 and Methodology	Section C.4 and Methodology
Competition (increased competition in service area)	Table 2, Cover Letter	Table 2, Cover Letter	Table 2, Cover Letter
Access by Service Area Residents (percentage of service area residents, PY3)	Section C.3	Section C.3	Section C.3
Access by Service Area Residents (number of service area residents, PY3)	Section C.3	Section C.3	Section C.3
Access by Medicare Patients (total Medicare dollars, gross revenue, PY3)	Form F.2b	Form F.2b	Form F.2b
Access by Medicare Patients (Medicare as a percent of gross revenue, PY3)	Form F.2b and Section C.3 <i>Mcare Rev / Total Rev</i>	Form F.2b and Section C.3 <i>Mcare Rev / Total Rev</i>	Form F.2b and Section C.3 <i>Mcare Rev / Total Rev</i>
Access by Medicare Patients (total Medicare procedures per scanner, PY3)	Form F.2b and Section C.2b <i>Mcare % Rev * Total Proc PY3</i>	Form F.2b and Section C.2b <i>Mcare % Rev * Total Proc PY3</i>	Form F.2b and Section C.2b <i>Mcare % Rev * Total Proc PY3</i>

ATTACHMENT C

Comparative Factor	RRLLC	WRLLC	DUHS
Access by Medicaid Patients (total dollars, gross revenue, PY3)	Form F.2b	Form F.2b	Form F.2b
Access by Medicaid Patients (Medicaid patients as a percent of gross revenue, PY3)	Form F.2b and Section C.3 <i>Mcaid Rev / Total Rev</i>	Form F.2b and Section C.3 <i>Mcaid Rev / Total Rev</i>	Form F.2b and Section C.3 <i>Mcaid Rev / Total Rev</i>
Access by Medicaid Patients (total Medicaid procedures per scanner, PY3)	Form F.2b and Section C.2b <i>Mcaid % Rev * Total Proc PY3</i>	Form F.2b and Section C.2b <i>Mcaid % Rev * Total Proc PY3</i>	Form F.2b and Section C.2b <i>Mcaid % Rev * Total Proc PY3</i>
Projected Average Net Revenue per MRI Procedure, PY3	Form F.2b and Form C.2b <i>Net Revenue / Total Proc</i>	Form F.2b and Form C.2b <i>Net Revenue / Total Proc</i>	Form F.2b and Form C.2b <i>Net Revenue / Total Proc</i>
Projected Average Operating Expense per MRI Procedure, PY3	Form F.3b and Form C.2b <i>Operating Exp / Total Proc</i>	Form F.3b and Form C.2b <i>Operating Exp / Total Proc</i>	Form F.3b and Form C.2b <i>Operating Exp / Total Proc</i>

ATTACHMENT D

Additional Letters of Support, Raleigh Radiology Knightdale

Date: 7/14/23

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: **Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina**

Dear Ms. Pittman,

I am writing this letter to express support for the Certificate of Need application from Raleigh Radiology, PLLC, to acquire one new fixed magnetic resonance imaging ("MRI") machine located at a Raleigh Radiology diagnostic center in Knightdale, on Great Falls Court.

As a clinician with patients who live in Wake County and nearby communities, I am pleased to welcome the proposed competitive alternative. Raleigh Radiology has a +70-year reputation for high-quality, affordable imaging services. The practice works with almost every third-party payor in this area and is a designated Provider of Choice for WakeMed Key Community Care, one of the largest Accountable Care Organizations in the state. Physician practices and diagnostic centers associated with Raleigh Radiology keep patient costs low while delivering high quality interpretations. Wake County desperately needs more MRI capacity. My staff can rarely find an affordable MRI schedule for our patients in less than a week.

I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I currently refer patients for MRI Yes No

In the past, I have ordered approximately 3 MRIs per month.

At Raleigh Radiology Knightdale, by 2025 I expect to order 1 MRIs per month.

My specialty is Nephrology

Signature: 

Name: Jason Eckel

Address: 790 SE Cary Plains

Phone: 919-235-0644

Suitland, Lenoir, NC

Practice Name: NC Nephrology

Email

Date: _____

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina

Dear Ms. Pittman,

I am writing this letter to express support for the Certificate of Need application from Raleigh Radiology, PLLC, to acquire one new fixed magnetic resonance imaging ("MRI") machine located at a Raleigh Radiology diagnostic center in Knightdale, on Great Falls Court.

As a clinician with patients who live in Wake County and nearby communities, I am pleased to welcome the proposed competitive alternative. Raleigh Radiology has a +70-year reputation for high-quality, affordable imaging services. The practice works with almost every third-party payor in this area and is a designated Provider of Choice for WakeMed Key Community Care, one of the largest Accountable Care Organizations in the state. Physician practices and diagnostic centers associated with Raleigh Radiology keep patient costs low while delivering high quality interpretations. Wake County desperately needs more MRI capacity. My staff can rarely find an affordable MRI schedule for our patients in less than a week.

I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I currently refer patients for MRI

Yes No

In the past, I have ordered approximately 1 MRIs per month.

At Raleigh Radiology Knightdale, by 2025 I expect to order 1 MRIs per month.

My specialty is Nephrology

Signature: [Handwritten Signature]

Name: Raymond Gresham

Practice Name:

Address:

Phone

Email

Date: 7/14/2023

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina

Dear Ms. Pittman,

I am writing this letter to express support for the Certificate of Need application from Raleigh Radiology, PLLC, to acquire one new fixed magnetic resonance imaging ("MRI") machine located at a Raleigh Radiology diagnostic center in Knightdale, on Great Falls Court.

As a clinician with patients who live in Wake County and nearby communities, I am pleased to welcome the proposed competitive alternative. Raleigh Radiology has a +70-year reputation for high-quality, affordable imaging services. The practice works with almost every third-party payor in this area and is a designated Provider of Choice for WakeMed Key Community Care, one of the largest Accountable Care Organizations in the state. Physician practices and diagnostic centers associated with Raleigh Radiology keep patient costs low while delivering high quality interpretations. Wake County desperately needs more MRI capacity. My staff can rarely find an affordable MRI schedule for our patients in less than a week.

I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I **currently refer** patients for MRI

Yes No

In the past, I **have ordered** approximately

2-3 MRIs ~~per month.~~ yr

At Raleigh Radiology Knightdale, **by 2025 I expect to order**

2-3 MRIs ~~per month.~~ yr

My specialty is

Nephrology

Signature:



Name:

Practice Name:

Address:

Phone

Email

Michael J. Casey, M.D.
3031 New Bern Ave., Suite 306
Raleigh, NC 27610
919-876-7807 / 919-876-8823 fax
NC License: 9800209
NPI: 1003894056
Tax ID: 81-2808787

Date: 7/17/23

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina

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I am writing this letter to express support for the Certificate of Need application from Raleigh Radiology, PLLC, to acquire one new fixed magnetic resonance imaging ("MRI") machine located at a Raleigh Radiology diagnostic center in Knightdale, on Great Falls Court.

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I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I **currently refer** patients for MRI Yes No

In the past, I **have ordered** approximately 6-8 MRIs per month.

At Raleigh Radiology Knightdale, **by 2025 I expect to order** 4 MRIs per month.

My specialty is Hematology/Oncology

Signature: Ryan Collier, PA-C

Name: Ryan Collier

Practice Name: WM Cancer Care

Address: 210 Ashville Ave #470

Phone: 919-350-8585

Email

Date: 7/17/23

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina

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I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I **currently refer** patients for MRI Yes No

In the past, I **have ordered** approximately 1-2 MRIs per month.

At Raleigh Radiology Knightdale, **by 2025 I expect to order** 4 MRIs per month.

My specialty is HEM/ONC

Signature: 

Name: SARAH HICKS MD

Practice Name: WAKEFIELD HEM/ONC

Address: 210 ASHVILLE AVE STE 440

Phone 919 350-2873

Email S.HICKS@WAKEMED.ORG

Date: 7/14/2023

Ms. Micheala Mitchell, Chief
Ms. Lisa Pittman, Assistant Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Letter of Support for Raleigh Radiology, PLLC Certificate of Need Application to acquire one new unit of fixed Magnetic Resonance Imaging Equipment, Wake County, North Carolina

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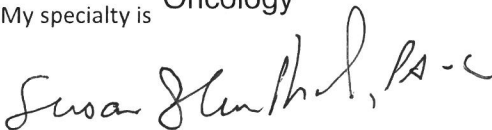
I expect to refer patients to Raleigh Radiology Knightdale should the service become available in 2024. My estimated referrals are based on the following assumptions:

I **currently refer** patients for MRI Yes No

In the past, I **have ordered** approximately **6-8** MRIs per month.

At Raleigh Radiology Knightdale, **by 2025 I expect to order** **2-3** MRIs per month.

My specialty is **Oncology**



Signature:

Name: **Susan Blumenthal, PA-C**

Practice Name: **Wake Med Cancer Center o**

Address: **210 Ashville Ave, Suite 440**

Phone **9190350-8585**

Email **sblumenthal@wakemed.org**

STATE OF NORTH CAROLINA
COUNTY OF WAKE

IN THE OFFICE OF
ADMINISTRATIVE HEARINGS
21 DHR 04543

<p>Pinnacle Health Services of North Carolina LLC d/b/a Cardinal Points Imaging of the Carolinas Wake Forest and Outpatient Imaging Affiliates LLC Petitioner,</p> <p>v.</p> <p>NC Department of Health and Human Services, Division of Health Service Regulation, Health Care Planning & Certificate of Need Section Respondent,</p> <p>and</p> <p>Duke University Health System Inc., Respondent-Intervenor.</p>	<p>FINAL DECISION</p>
------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------

THIS MATTER came for hearing before Administrative Law Judge Melissa Owens Lassiter on March 7-16, 2022, in Raleigh, North Carolina to hear Petitioner’s contested case petition, filed pursuant to N.C. Gen. Stat. §§ 150B-23 and 131E-188, appealing Respondent’s September 24, 2021 Agency decision and Required State Agency Findings, to approve, with conditions, a Certificate of Need application by Respondent-Intervenor to acquire one new fixed MRI scanner in a new diagnostic center in Raleigh, North Carolina, and to disapprove Petitioner’s competing Certificate of Need application for one fixed MRI scanner at its existing facility in Wake Forest, North Carolina.

Thereafter, pursuant to the Tribunal’s Order, the parties filed their respective proposed Final Decisions. Having heard and considered all of the testimony and evidence in this case and having considered the exhibits, arguments, and relevant law, the Undersigned makes the Findings of Fact by a preponderance of the evidence, enters her Conclusions of Law thereon, and makes the following Final Decision:

APPEARANCES

52. Here, the Agency's purported analysis was based on the "historical utilization of each applicant." Contradicting the data it collected and analyzed, the Agency erroneously concluded that Pinnacle and Duke "have no historical utilization with a fixed MRI scanner."

53. Pinnacle projected the highest historical utilization per scanner and should have been found "more effective" with respect to the historical utilization factor. The Agency's determination that this factor was inconclusive was erroneous because it failed to follow any course of reasoning, disregarded facts and/or law, and failed to follow any determining principle. *See Donnelly*, 236 N.C. App. at 37, 763 S.E.2d at 158.

Summary of Comparative Analysis

54. The Agency determined that Duke was more effective as to two factors (Geographic Accessibility and Access to Service Area Residents). As discussed above, the evidence in this case demonstrates that the Agency acted erroneously in determining that the Duke Application was more effective with respect to Geographic Accessibility. Instead, Pinnacle's application should have been found more effective. Correcting this error alone, the comparative analysis is tied, with Duke and Pinnacle each being more effective as to one factor. (*See Meyer*, Tr. p. 1633).

55. As discussed above, the evidence in this case also demonstrates that the Agency erred by concluding that a comparison could not be drawn on the Projected Average Operating Expense per Procedure factor. Because there are no circumstances under which Duke's projected operating expense per procedure could be lower than Pinnacle's, the only rational conclusion is that the Pinnacle Application was more effective with respect to this factor. Correcting this error in addition to the error on geographic accessibility, the results of the comparative analysis are Pinnacle is more effective on two factors and Duke is more effective on one factor. (*See Meyer*, Tr. pp. 1633-34).

56. As the Agency witnesses testified, if Pinnacle is more effective on two factors and Duke is more effective on one factor, Pinnacle should be the approved applicant and is entitled to the CON. (*See Yakaboski*, Tr. p 175; *Pittman*, Tr. pp. 486-87).

57. This result is unchanged by the outcome of either the Historical Utilization or Average Net Revenue per Procedure factors, although correcting the Historical Utilization factor as discussed above would reinforce this result by adding a third factor on which Pinnacle was more effective.

Substantial Prejudice

58. Pinnacle met its burden of demonstrating that the Agency substantially prejudiced its rights in denying Pinnacle's application for a CON and instead awarding a CON to Duke.

59. The Pinnacle Application was conforming to all applicable statutory criteria and rules, and it demonstrated a need for a fixed MRI scanner at its Wake Forest facility.

county where the contested case which resulted in the final decision was filed. **The appealing party must file the petition within 30 days after being served with a written copy of the Administrative Law Judge's Final Decision.**

In conformity with the Office of Administrative Hearings' rule, 26 N.C. Admin. Code 03.0102, and the Rules of Civil Procedure, N.C. General Statute 1A-1, Article 2, **this Final Decision was served on the parties as indicated by the Certificate of Service attached to this Final Decision.** N.C. Gen. Stat. § 150B-46 describes the contents of the Petition and requires service of the Petition on all parties. Under N.C. Gen. Stat. § 150B-47, the Office of Administrative Hearings is required to file the official record in the contested case with the Clerk of Superior Court within 30 days of receipt of the Petition for Judicial Review. Consequently, a copy of the Petition for Judicial Review must be sent to the Office of Administrative Hearings at the time the appeal is initiated in order to ensure the timely filing of the record.

IT IS SO ORDERED.

This the 19th day of July, 2022.



Melissa Owens Lassiter
Administrative Law Judge

CERTIFICATE OF SERVICE

The undersigned certifies that, on the date shown below, the Office of Administrative Hearings sent the foregoing document to the persons named below at the addresses shown below, by electronic service as defined in 26 NCAC 03 .0501(4), or by placing a copy thereof, enclosed in a wrapper addressed to the person to be served, into the custody of the North Carolina Mail Service Center which subsequently will place the foregoing document into an official depository of the United States Postal Service.

Elizabeth Sims Hedrick
Fox Rothschild LLP
ehedrick@foxrothschild.com
Attorney For Petitioner

Marcus C. Hewitt
Fox Rothschild LLP
mhewitt@foxrothschild.com
Attorney For Petitioner

Kimberly M. Randolph
N.C. Department of Justice, Health
Service Section
krandolph@ncdoj.gov
Attorney For Respondent

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Intervenor

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Intervenor

Kenneth L Burgess
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Attorney for Respondent-
Intervenor

Matthew Aaron Fisher
Baker, Donelson, Bearman, Caldwell &
Berkowitz P.C.
MFisher@BakerDonelson.com
Attorney for Respondent-
Intervenor

This the 19th day of July, 2022.



Christine E. Cline
Law Clerk
N.C. Office of Administrative Hearings
1711 New Hope Church Road
Raleigh, NC 27609-6285
Phone: 984-236-1850

August 29, 2022 **ATTACHMENT F**

ACR Changes CT and MRI Accreditation Contrast Media Supervision Requirements

[Recommend](#) [Bookmark](#)

The American College of Radiology® (ACR®) Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) Accreditation Committees have announced that a radiologist (MD/DO) will now provide direct or general supervision of intravenous contrast material administration and ensure compliance with guidance provided in the [ACR Manual on Contrast Media \(/Clinical-Resources/Contrast-Manual\)](#). Also, in line with the [ACR-SPR Practice Parameter for the Use of IV Contrast Media \(-/media/ACR/Files/Practice-Parameters/IVCM.pdf\)](#), and recognizing a range of responsible providers trained in and capable of managing an acute hypersensitivity reaction under general supervision of a radiologist, the following providers may provide direct supervision of intravenous contrast administration:

1. Non-radiologist physicians (MD/DO).
2. Advanced practice providers (nurse practitioner, physician assistant).
3. Registered nurses following a symptom- and sign-driven treatment algorithm.

The provider of direct supervision must be immediately available to furnish assistance and direction throughout the performance of the procedure. This does not mean that the supervising provider or radiologist must be present in the room where and when the procedure is performed.

However, there should be at least one person who can recognize adverse events related to contrast media administration in attendance (in the room or in an adjacent control room) to observe the patient during and immediately after the injection and summon medical assistance as needed.

All local and state regulations regarding supervision of contrast media administration must be followed.

For more information, consult the [ACR Manual on Contrast Media \(/Clinical-Resources/Contrast-Manual\)](#) and the [ACR-SPR Practice Parameter for the Use of IV Contrast Media \(-/media/ACR/Files/Practice-Parameters/IVCM.pdf\)](#).

ATTACHMENT G

Blue Cross Blue Shield Cost Comparison

It is important to note that while direct out of pocket cost for this insurance plan is \$0, regardless of site of service, the **plan cost for the service** varies widely among the providers. These costs are negotiated by the provider with the insurance company. The results are then passed on to the patients and employers in the form of increased premiums.

The following data was accessed on July 19, 2023. Costs are specific to Raleigh Radiology Knightdale (“RRKD”) and Wake Radiology Cary (“WRCary”); because Duke Garner does not exist, Duke Imaging at Cary Parkway (“Duke Cary”) was used as a proxy. It should be noted that Duke Imaging locations do not bill globally, the plan costs listed below are technical only, a second cost to the insurance company will be filed for the professional.

MRI With and Without Contrast, Abdomen

RRKD	WRCary	Duke Cary
\$999	\$2,551	\$1,416

MRI With and Without Contrast, Lower Limb

RRKD	WRCary	Duke Cary
\$989	\$2,520	\$1,421

MRI With and Without Contrast, Spine

RRKD	WRCary	Duke Cary
\$940	\$2,609	\$1,482

i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Abdomen at Raleigh Radiology**

THIS LOCATION

Raleigh Radiology

1101 Great Falls Ct, Knightdale, NC 27545

Get directions (est. 1.3 miles away)

OTHER LOCATIONS

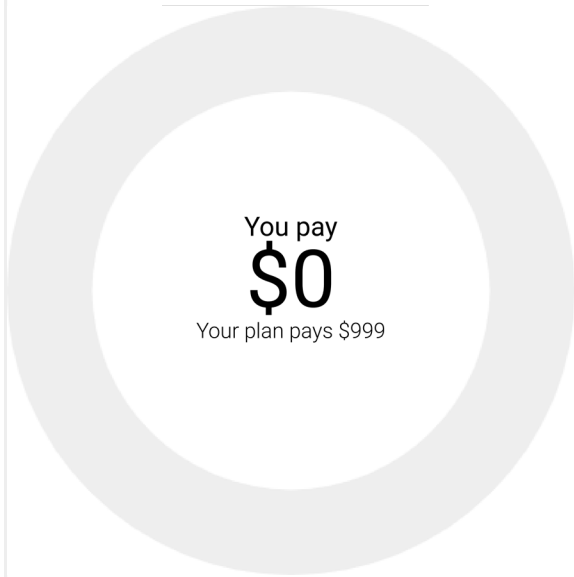
See your cost at their other locations **v**

COST ASSISTANT

Save up to **\$195** with similar providers

See your savings

Viewing cost details ^{For} **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$999

Total cost

\$999

Individual Benefit Contributions

Deductible **i**

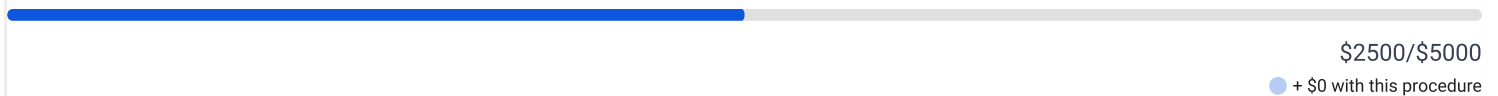


Out of Pocket Maximum **i**



Family Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**



i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Lower Limb at Raleigh Radiology**

THIS LOCATION

Raleigh Radiology

1101 Great Falls Ct, Knightdale, NC 27545

Get directions (est. 1.3 miles away)

OTHER LOCATIONS

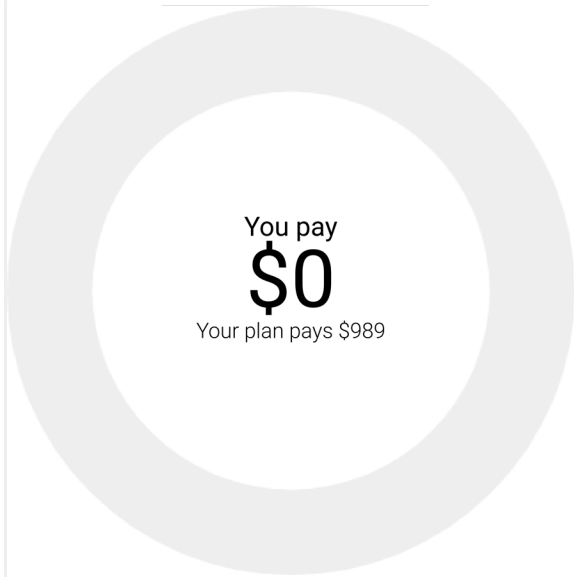
See your cost at their other locations **v**

COST ASSISTANT

Save up to **\$221** with similar providers

See your savings

Viewing cost details ^{For} **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$989

Total cost

\$989

Individual Benefit Contributions

Deductible **i**

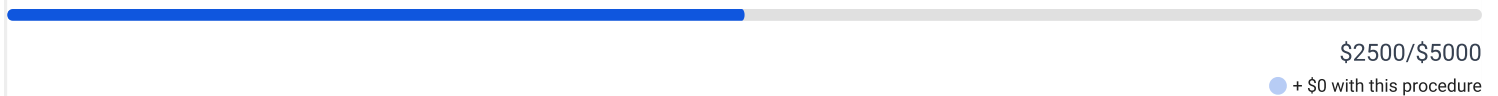


Out of Pocket Maximum **i**



Family Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**



Estimated Procedure Cost for MRI (without and with Contrast), Spine at Raleigh Radiology

THIS LOCATION

Raleigh Radiology

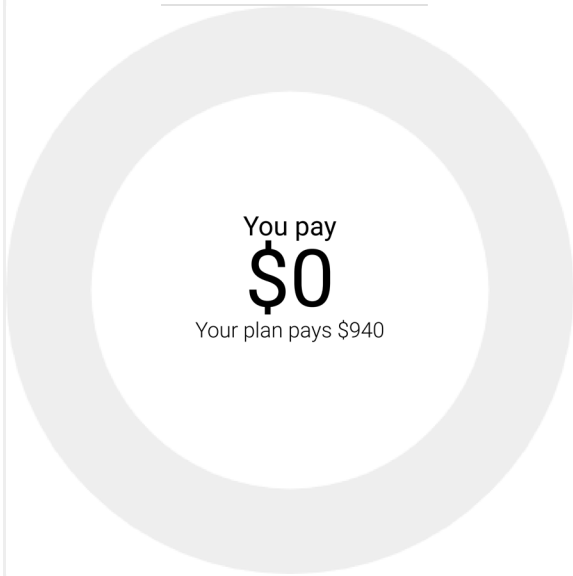
1101 Great Falls Ct, Knightdale, NC 27545

OTHER LOCATIONS

See your cost at their other locations

[Get directions](#) (est. 1.3 miles away)

For
Viewing cost details **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$940

Total cost

\$940

Individual Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ



Family Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ



i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Abdomen at Wake Radiology Diagnostic Imaging**

THIS LOCATION

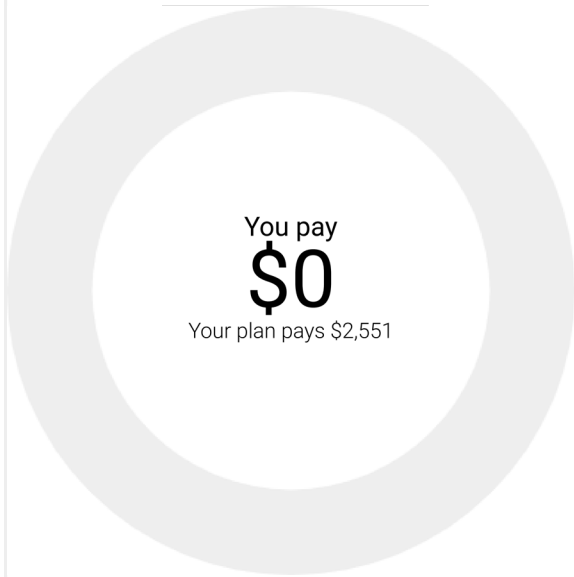
Wake Radiology Cary Mri/Pet-Ct
300 Ashville Ave Ste 180, Cary, NC 27518

Get directions (est. 17.7 miles away)

OTHER LOCATIONS

See your cost at their other locations **v**

For
Viewing cost details **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$2,551

Total cost

\$2,551

Individual Benefit Contributions

Deductible **i**

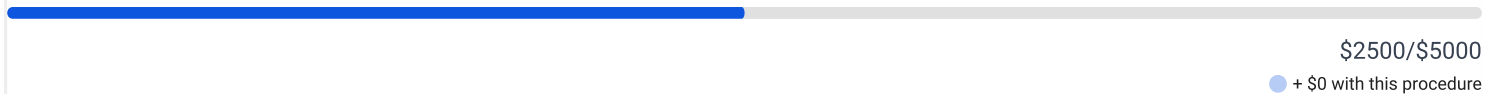


Out of Pocket Maximum **i**



Family Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**



i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Lower Limb at Wake Radiology Diagnostic Imaging**

THIS LOCATION

Wake Radiology Cary Breast Center
300 Ashville Ave Ste 260, Cary, NC 27518

Get directions (est. 17.7 miles away)

OTHER LOCATIONS

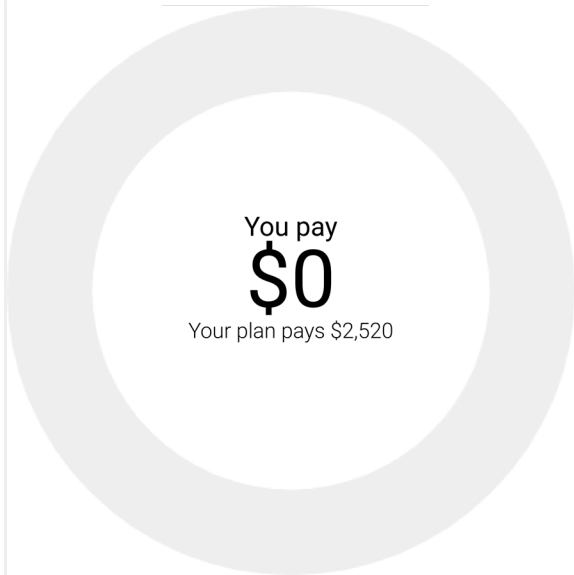
See your cost at their other locations **v**

COST ASSISTANT

Save up to **\$1,752** with similar providers

See your savings

For
Viewing cost details **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$2,520

Total cost

\$2,520

Individual Benefit Contributions

Deductible **i**

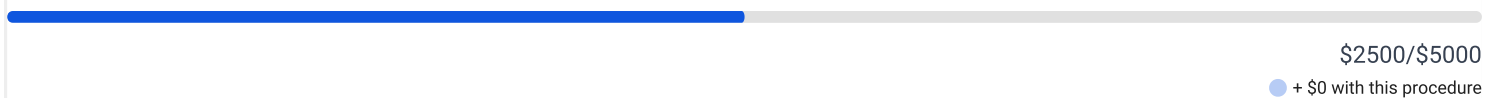


Out of Pocket Maximum **i**



Family Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**



i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Spine at Wake Radiology Diagnostic Imaging**

THIS LOCATION

Wake Radiology Cary Mri/Pet-Ct
300 Ashville Ave Ste 180, Cary, NC 27518

Get directions (est. 17.7 miles away)

OTHER LOCATIONS

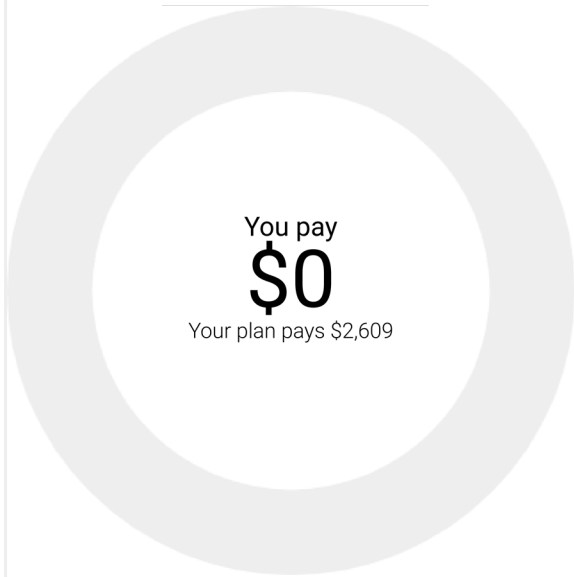
See your cost at their other locations **v**

COST ASSISTANT

Save up to **\$1,922** with similar providers

See your savings

For
Viewing cost details **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$2,609

Total cost

\$2,609

Individual Benefit Contributions

Deductible **i**

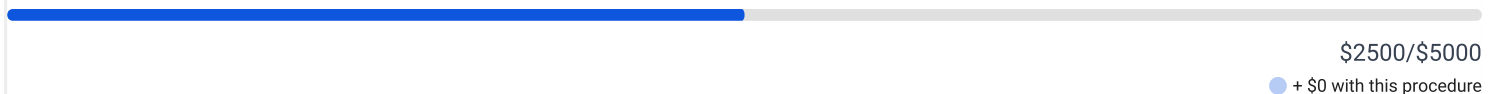


Out of Pocket Maximum **i**



Family Benefit Contributions

Deductible **i**



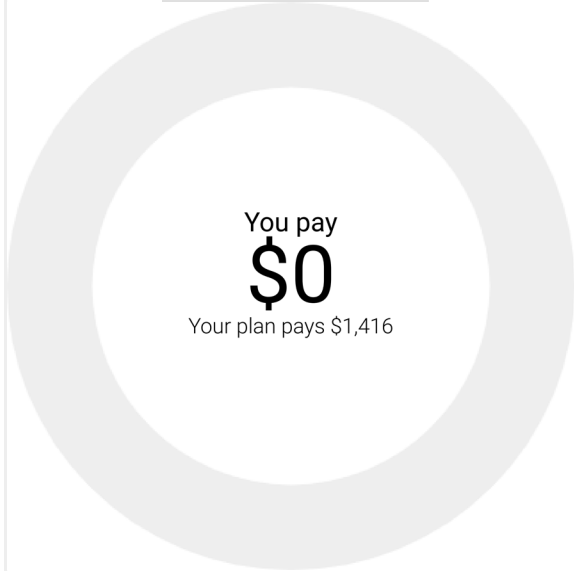
Out of Pocket Maximum **i**



i The information provided in this tool is for informational purposes only. Out-of-pocket estimate information is only available for claims that have been processed.

Estimated Procedure Cost for **MRI (without and with Contrast), Abdomen at Duke Imaging Svcs At Cary Parkway**

For
Viewing cost details KELLY IVEY



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

\$1,416

Total cost

\$1,416

Individual Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**

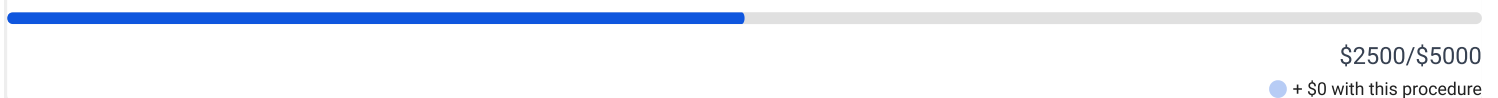


Family Benefit Contributions

Deductible **i**



Out of Pocket Maximum **i**



Estimated Procedure Cost for MRI (without and with Contrast), Lower Limb at Duke Imaging Svcs At Cary Parkway

THIS LOCATION

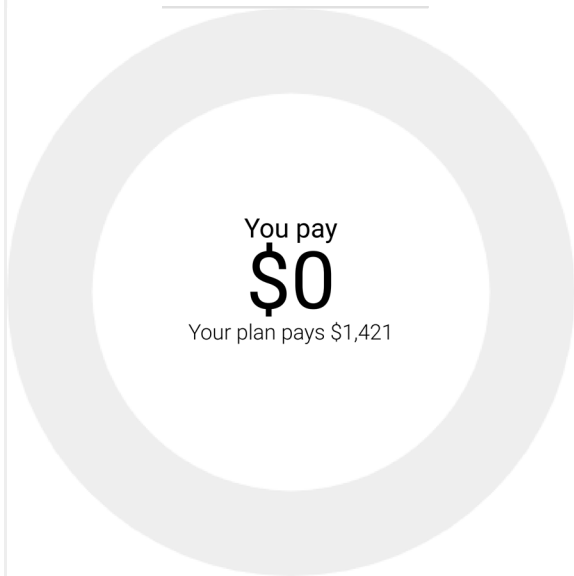
Duke Imaging Services At Cary Parkway- Fixed Ct
3700 NW Cary Pkwy Ste 120 Rm 110, Cary, NC
27513

COST ASSISTANT

Save up to **\$653** with similar providers
See your savings

[Get directions](#) (est. 19.2 miles away)

Viewing cost details For **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

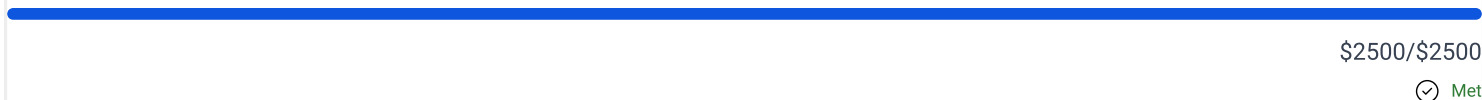
\$1,421

Total cost

\$1,421

Individual Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ



Family Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ



Estimated Procedure Cost for MRI (without and with Contrast), Spine at Duke Imaging Svcs At Cary Parkway

THIS LOCATION

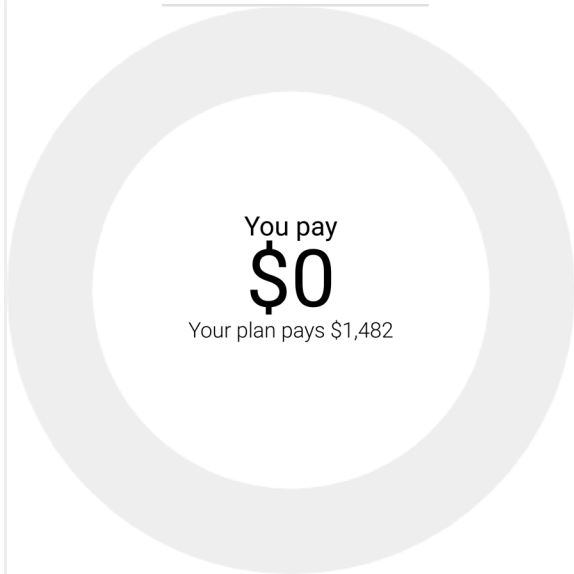
Duke Imaging Services At Cary Parkway- Fixed Ct
3700 NW Cary Pkwy Ste 120 Rm 110, Cary, NC
27513

COST ASSISTANT

Save up to **\$795** with similar providers
See your savings

[Get directions](#) (est. 19.2 miles away)

Viewing cost details For **KELLY IVEY**



You pay towards your copay

\$0

You pay towards your deductible

\$0

You pay towards coinsurance

\$0

Your plan pays

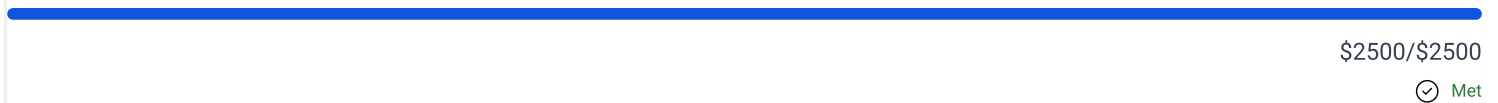
\$1,482

Total cost

\$1,482

Individual Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ

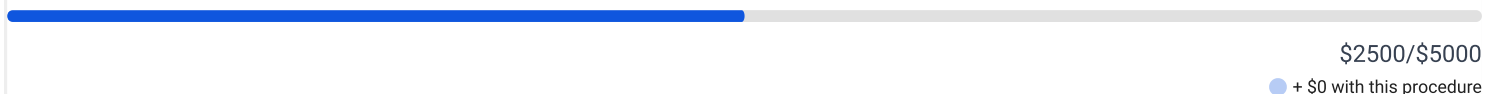


Family Benefit Contributions

Deductible ⓘ



Out of Pocket Maximum ⓘ



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The American College of Radiology will periodically define new practice parameters and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice parameters and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice parameter and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review and approval. The practice parameters and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice parameter and technical standard by those entities not providing these services is not authorized.

Revised 2021 (Resolution 42)*

ACR–NASCI–SPR PRACTICE PARAMETER FOR THE PERFORMANCE AND INTERPRETATION OF CARDIAC MAGNETIC RESONANCE IMAGING (MRI)

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner in light of all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR), the North American Society for Cardiovascular Imaging (NASCI), and the Society for Pediatric Radiology (SPR).

A. Cardiac magnetic resonance imaging (MRI) is an established imaging modality, well recognized for its value in the assessment and monitoring of a wide range of diseases of the heart and surrounding related structures (eg, pericardium) [1,2]. Historically, imaging has played a critical role in the diagnosis and evaluation of acquired and congenital cardiac disease, beginning with chest radiography and fluoroscopy and progressing to coronary angiography and cardiac catheterization, echocardiography, and nuclear medicine. All of these modalities have a well-established role in patient care. Multidetector computed tomography (MDCT) and MRI, with appropriately equipped scanners, can also acquire images of coronary arteries, cardiac chambers, valves, myocardium, and pericardium in order to view cardiac anatomy. Furthermore, MRI methods also permit the evaluation of regional and global cardiac function. Thus, CT and MRI continue to play an increasing role in comprehensive cardiac imaging. This document deals specifically with cardiac MRI applications.

The technical parameters and field of view (FOV) of a cardiac MRI examination need to be appropriately tailored to evaluate the cardiac anatomy and/or function in question. However, the images obtained will also show adjacent anatomy, often including portions of the lungs, mediastinum, spine, and upper abdomen. Furthermore, cardiac MRI protocols may involve evaluation of extracardiac vascular structures within and beyond the thorax, which may reveal clinically significant noncardiac findings [3-5]. In addition to examining the cardiac structures of interest, the interpreting imaging physician is responsible for examining all the visualized noncardiac structures and must report any clinically relevant abnormalities of these adjacent structures. In some cases, these structures may be seen only on localizing (scout) images.

Cardiac MRI also presents potential patient safety issues. These issues pertain primarily to the strong magnetic field and its potential impact on implanted devices. It should be noted that many devices, including several cardiac pacemakers, are now MRI conditional, permitting safe MR imaging in these patients when Food and Drug Administration (FDA) and the manufacturer's guidelines are followed [6]. In addition, it has been shown that scanning pacemakers under certain strictly monitored conditions can be performed safely [7,8] (see Section IV). Other safety issues include radiofrequency (RF) heating of implants, those associated with MRI contrast agents and patient sedation. Although uncommon, gadolinium-based contrast agents can cause allergic reactions or can place patients at risk for nephrogenic systemic fibrosis (NSF) when administered in patients with renal failure. A significant percentage of cardiac MRIs are performed with intravenous contrast agents. For more information, refer to the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [9] and [ACR Manual on Contrast Media](#) [10].

Radiologists, because of their extensive experience with MRI, have an important role in its application to the heart. Most radiologists already supervise and interpret MRI and CT scans of the chest (which include basic evaluation of the pericardium, heart size, and cardiac masses) and perform MR angiography (MRA). Their knowledge of structures beyond the heart provides added value in cardiac imaging. They already supervise MRI equipment performance, standard operating procedures, safety regulations, and personnel. Their prior experience with MRI shortens their learning curve for cardiac MRI applications.

B. MRI has the following important attributes and capabilities that make it advantageous for evaluating the adult or pediatric heart:

1. High natural contrast exists between the intracardiac/intravascular blood pool and the surrounding cardiac and vascular structures due to inherent tissue characteristics. For example, cardiac anatomy and pericardial and mediastinal abnormalities can be depicted with "black-blood" fast spin-echo imaging [11]. "Bright-blood" gradient-echo-based cine sequences can be used to show cardiac anatomy, myocardial wall motion and thickening, artifacts generated by turbulent blood flow and valve leaflet motion, and valve disease [12,13]. Consequently, contrast agents are not routinely required for discrimination of the blood pool and evaluation of cardiac function. Contrast administration has become a key component in MR myocardial perfusion techniques, angiographic techniques, and late gadolinium enhancement (LGE) imaging for

Indications for evaluation of the aorta, pulmonary artery, pulmonary veins, and systemic veins in the setting of congenital heart disease are covered by the practice parameters for MRA. For further information, see the [ACR–NASCI–SPR Practice Parameter for the Performance of Body Magnetic Resonance Angiography \(MRA\)](#) [101].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [9] for physician qualifications to interpret noncardiac MRI examinations. Of note, that practice parameter specifically states that additional qualifications are needed for cardiac MRI interpretation.

A. Physician

The physician is responsible for all aspects of the study, including, but not limited to, reviewing all indications for the examination, specifying the pulse sequences to be performed, specifying the imaging planes, specifying the use and dosage of contrast media, interpreting images, generating an official interpretation,² and ensuring the quality of the images and the interpretation.

1. Physician with prior qualifications in general MRI

The radiologist or other physician who meets the qualifications of the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [9] for all anatomic areas will have substantial knowledge of the physics of MRI; the principles of MR image acquisition and postprocessing, including use of diagnostic workstations; the design of MR protocols, including pulse sequences; and the rate and timing of contrast administration. The physician also will have substantial experience in MRI interpretation, including MRI of extracardiac thoracic structures that will be included in the cardiac MRI examination and MRA. Some of these physicians will also have substantial experience in other methods of cardiac MRI and in assessing cardiac function and/or will have specific experience in cardiac MRI. However, in order to achieve competency in all aspects of cardiac MRI, many physicians will require additional education in cardiac anatomy, physiology, pathology, and/or cardiac MRI.

The supervising and interpreting physician with prior qualifications in general MRI should also meet 1 of the following requirements:

- a. Training in cardiac MRI in a training program approved by the Accreditation Council for Graduate Medical Education (ACGME), the Royal College of Physicians and Surgeons of Canada (RCPSC), the Collège des Médecins du Québec, or the American Osteopathic Association (AOA) to include:
 - i. CME in cardiac anatomy, physiology, pathology, and cardiac MRI
and
 - ii. The interpretation, reporting, and/or supervised review of cardiac MRI examinations
or
- b. Completion of Category I CME in cardiac imaging, including:
 - i. Cardiac MRI, anatomy, physiology, and/or pathology, or documented equivalent supervised experience in a center actively performing cardiac MRI
andThe interpretation, reporting, and/or supervised review of cardiac MRI examinations

2. Physician without prior qualifications in general MRI

The radiologist or other physician who does not meet the qualifications of the [ACR Practice Parameter for Performing and Interpreting Magnetic Resonance Imaging \(MRI\)](#) [9] for all anatomic areas requires more extensive training and experience in MRI, with an emphasis on cardiac MRI. In addition to specific

²The ACR Medical Legal Committee defines official interpretation as that written report (and any supplements or amendments thereto) that attach to the patient's permanent record. In health care facilities with a privilege delineation system, such a written report is prepared only by a qualified physician who has been granted specific delineated clinical privileges for that purpose by the facility's governing body upon the recommendation of the medical staff.

instruction in imaging interpretation, this training must include the physics of MRI, MRI safety, the principles of MRI acquisition and postprocessing, including use of diagnostic workstations, and the design of MRI protocols, including pulse sequences and the rate and timing of contrast administration. Some physicians will also require additional education in cardiac anatomy, physiology, and pathology.

The supervising and interpreting physician without prior qualifications in general MRI should meet the following requirements:

- a. Completion of an ACGME-approved training program in the specialty practiced, plus Category I CME in MRI, including, but not limited to: MRI physics; recognition of MRI artifacts; safety, instrumentation, and clinical applications of MRI in cardiac and thoracic MRI
and
- b. Supervision, interpretation, and reporting of MRI cases in a supervised situation with an emphasis on thoracic MRI and cardiac MRI, including the interpretation, reporting, and/or supervised review of cardiac MRI examinations

3. Pharmacologic stress testing and administration of other pharmacologic agents

Physicians performing pharmacologic stress testing or administering other pharmacologic agents as part of cardiac MRI should be knowledgeable about the administration, risks, and contraindications of the pharmacologic agents used and should be capable of monitoring the patient throughout the procedure.

Personnel monitoring stress-induced studies should have current Advanced Cardiac Life Support (ACLS) certification.

4. Maintenance of competence

All physicians performing cardiac MRI examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is ensured primarily on the basis of continuing experience, interpretation or review of a sufficient number of examinations in order to maintain the physician's skills.

5. Continuing medical education (CME)

The physician's CME should be in accordance with the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [102] of approved education and should include CME in cardiac MRI as is appropriate to the physician's practice needs.

6. Additional training recommendations

Physicians supervising a cardiac MRI service (creating scan protocols, administering a quality assurance program, and/or training of others in cardiac MRI) are expected to have additional training in the performance, interpretation, and reporting of cardiac MRI examinations, the pathophysiology of congenital and acquired cardiac diseases, MRI technologies, and MRI safety.

B. Qualified Medical Physicist/MR Scientist

The personnel qualified to carry out acceptance testing and monitoring of MRI equipment for the purposes of this parameter include a qualified medical physicist or a qualified MR scientist.

A qualified medical physicist is an individual who is competent to practice independently in 1 or more subfields of medical physics. The ACR considers certification, continuing education, and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice in 1 or more subfields of medical physics, and to be a qualified medical physicist. The ACR strongly recommends that the individual be certified in the appropriate

subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, the American Board of Science in Nuclear Medicine (ABSNM), or the American Board of Medical Physics (ABMP).

A qualified medical physicist/MR scientist should meet the [ACR Practice Parameter for Continuing Medical Education \(CME\)](#) [102] ~~[102]~~.

The appropriate subfield of medical physics for this practice parameter is diagnostic medical physics (previous medical physics certification categories to include radiological physics, diagnostic radiological physics, and diagnostic imaging physics are also acceptable). (ACR Resolution 17, adopted in 1996 – revised in 2008, 2012, 2022, Resolution 41f)

A qualified MR scientist is an individual who has obtained a graduate degree in a physical science involving nuclear magnetic resonance (NMR) or MRI by the ABMP in magnetic imaging physics.

These individuals should have 3 years of documented experience in a clinical MR environment.

The qualified medical physicist/MR scientist must be familiar with the principles of MRI safety for patients, personnel, and the public; the FDA’s guidance for MRI diagnostic devices; and other regulations pertaining to the performance of the equipment being monitored. The qualified medical physicist/MR scientist should be knowledgeable in the field of NMR physics and familiar with MRI technology, including function, clinical uses, and performance specifications of MRI equipment, as well as calibration processes and limitations of the performance testing hardware, procedures, and algorithms. The qualified medical physicist/MR scientist should have a working understanding of clinical imaging protocols and methods of their optimization, with a desired focus on cardiac imaging. This proficiency should be maintained by participation in continuing education programs of sufficient frequency to ensure familiarity with current concepts, equipment, and procedures.

The qualified medical physicist/MR scientist may be assisted in obtaining test data for performance monitoring by other properly trained individuals. These individuals must be properly trained and approved by the qualified medical physicist/MR scientist in the techniques of performing the tests, the function and limitations of the imaging equipment and test instruments, the reason for the tests, and the importance of the test results. The qualified medical physicist/MR scientist must review and approve all measurements.

C. Non-Physician Radiology Provider (NPRP)

NPRPs are all Non-Physician Providers (eg, RRA, RPA, RA, PA, NP, ...) who assist with or participate in portions of the practice of a radiologist-led team (Radiologists = diagnostic, interventional, neurointerventional radiologists, radiation oncologists, and nuclear medicine physicians). The term “NPRP” does not include radiology, CT, US, NM MRI technologists, or radiation therapists who have specific training for radiology related tasks (eg, acquisition of images, operation of imaging and therapeutic equipment) that are not typically performed by radiologists.

The term 'radiologist-led team' is defined as a team supervised by a radiologist (ie, diagnostic, interventional, neurointerventional radiologist, radiation oncologist, and nuclear medicine physician) and consists of additional healthcare providers including RRAs, PAs, NPs, and other personnel critical to the provision of the highest quality of healthcare to patients. (ACR Resolution 8, adopted 2020).

1. Registered Radiologist Assistant (RRA)

An RRA is an advanced level radiographer who is certified and registered as a “Registered Radiologist Assistant” by the American Registry of Radiologic Technologists (ARRT) after successful completion of an advanced academic program encompassing an American Society of Radiologic Technologists (ASRT) RRA curriculum and a radiologist-directed clinical preceptorship.

Under radiologist supervision, the RRA may perform patient assessment, patient management, and selected examinations as delineated in the ACR Statement “Radiologist Assistant: Roles and Responsibilities” subject to state law (see the [ACR Digest of Council Actions Appendix H](#)). The RRA transmits to the supervising

radiologist those observations that have a bearing on diagnosis. Performance of diagnostic interpretations (preliminary, final, or otherwise) remains outside the scope of practice of the RRA. RRAs performing invasive or non-invasive procedures should function under radiologist supervision and as part of radiologist-led teams. (Adopted 2006 Resolution 34, 2016 Resolution 1-c, Revised in 2020 Resolution 11).

The RRA performing cardiac MRI should have advanced certification in MRI and should have supervised experience in performing cardiac MRI examinations. The radiologist assistant's continuing education credits should include continuing education in cardiac CT performance as is appropriate to his or her practice needs. Basic life support (BLS) and automatic defibrillator (AED) training is recommended.

D. Radiologic Technologist

The technologist should participate in ensuring patient comfort and safety in preparing and positioning the patient for the MRI examination to include proper positioning of the ECG leads and obtaining the MRI data in a manner suitable for interpretation by the physician.

The technologist performing cardiac MRI should be certified by the ARRT or the Canadian Association of Medical Radiation Technologists (CAMRT). It is recommended that the technologist performing cardiac MRI have advanced certification in MR. Each technologist should have supervised experience in performing cardiac MRI examinations and in the intravenous administration of conventional MR contrast media. If intravenous contrast material is to be administered, the qualifications for technologists performing intravenous injections should be in compliance with current ACR policy³ and with existing operating procedures or manuals at the imaging facility. The technologist's continuing education credits should include continuing education in cardiac MRI as is appropriate to his or her practice needs. Basic life support (BLS) and automatic defibrillator (AED) training is recommended.

Any technologist practicing MRI scanning should be licensed in the jurisdiction in which he or she practices if state licensure exists. To ensure competence, all technologists must be evaluated by the supervising physician [103].

IV. SAFETY GUIDELINES AND POSSIBLE CONTRAINDICATIONS

In all cases, a risk/benefit analysis for each patient should be performed prior to MRI scanning. The cardiac MRI physician should have thorough knowledge of patient safety, including proper patient and/or accompanying person screening, specific absorption rate limits, possible neurological effects, tissue heat deposition, risks and benefits of contrast media administration, and contraindications for performance of MRI, such as certain implantable devices [104]. Prior to MRI, patient screening should include determination of implantable devices, and operators should determine whether the devices are "MR safe," "MR conditional," or "not MR safe." Although the performance of MRI in patients with pacemakers or implantable cardioverter defibrillators (ICDs) that are not MRI conditional has been reported, this practice is not currently routine and should only occur under strictly monitored conditions and parameters [105]. In addition, each case should be reviewed for risk/benefit. **If cardiac MRI is to be performed in patients with a pacemaker or other non-MRI conditional device, it is recommended that proper personnel be present during the examination. They should include a physician or technical staff that is capable of programming or adjusting the implanted device should reprogramming be required [8]. In instances in which device type or its safety cannot be determined, risk/benefit should be determined by the appropriate imaging physician (in consultation with the referring cardiologist), and patient should be informed and/or consented for the procedure.**

Regarding the administration of intravenous (IV) contrast media, the physician should supervise patient selection to identify those patients for whom IV contrast media administration may present an increased risk or be contraindicated. Reactions occur less frequently with gadolinium-based contrast media in comparison with iodinated media. For pretreatment considerations in these patients, please see the [ACR Manual on Contrast Media](#) [10]. In patients with severely impaired renal function, the risk of nephrogenic systemic fibrosis (NSF) should be compared against the potential benefits for contrast-enhanced MRI using gadolinium-based contrast media and/or alternate non-MRI forms of imaging [104]. The physician should also be available to treat adverse reactions to IV

³See the [ACR-SPR Practice Parameter for the Use of Intravascular Contrast Media](#).



The Value of Medicaid

Providing Access to Care and Preventive Health Services

APRIL 2018

The Value of Medicaid: Access to Care

Key Takeaways



Adults and children enrolled in a Medicaid health plan had significantly better access to care and preventive services than people with no health coverage.



Overall, this analysis demonstrates a consistent pattern of strong, statistically significant relationships between insurance coverage—whether commercial or Medicaid—and access to care and preventive care services.



The findings from this study refute outdated, less rigorous studies that question the value of Medicaid, and add to the growing number of recent studies that demonstrate the value of having insurance coverage generally, and Medicaid more specifically.

Summary

Over 74 million Americans are currently insured under Medicaid and the Children's Health Insurance Program (CHIP), according to the Centers for Medicare and Medicaid Services.¹ More than 52 million low-income individuals—representing nearly 70 percent of total Medicaid enrollment—rely on private health plans for their Medicaid coverage.² Since its inception in the mid-1960s, the Medicaid program has provided needed financial security to millions of Americans. Medicaid has consistently proven to be a valuable and reliable source of access to health care to the millions of vulnerable enrollees who need it most.³⁻⁵

Recent studies of people with Medicaid coverage have found they have access to care⁶⁻¹² and use preventive care services¹³⁻¹⁶ at rates comparable to those with commercial insurance; both groups have far better experiences than the uninsured. However, some critics of the Medicaid program have raised questions about patient access to care and quality based on several commonly cited studies that include outdated data and/or methodological weaknesses that challenge the validity and generalizability of their conclusions.¹⁷⁻²⁰

To assess the nature of care Medicaid enrollees receive, AHIP researchers analyzed data from the Medical Expenditure Panel Survey (MEPS) of Medicaid beneficiaries, and people covered by commercial insurance, as well as the uninsured. Specifically, we compared measures of access to care and the provision of preventive services to people enrolled in a Medicaid health plan or those covered by a commercial health plan with those who were uninsured during the 2013-2015 timeframe.

The Value of Medicaid: Access to Care

As a secondary analysis, the same analyses were conducted for enrollees of Medicaid health plans vs. commercial health plans vs. uninsured during the 2007-2009 timeframe, in order to describe any changes in care access and preventive services before the passage of the Affordable Care Act.

We found that adults and children enrolled in a Medicaid health plan had significantly better access to care and preventive services than people with no health coverage. For example:

- Adult Medicaid enrollees were almost five times more likely, and children were four times more likely, to have a usual source of care than people with no health coverage.
- Adults were more than four times more likely, and children were two-to-three times more likely, to receive certain preventive care services than people with no health insurance.

Overall, this analysis shows a consistent pattern of strong, statistically significant relationships between insurance coverage—whether commercial or Medicaid—and access to care and preventive care services:

- Across multiple measures, people with Medicaid coverage reported better access than people with no health insurance.
- Adults and children enrolled in Medicaid health plans appeared to have access to care and preventive services at levels similar to people who have commercial health coverage.

The findings from this study refute outdated, less rigorous studies that question the value of Medicaid, and add to the growing number of recent studies that demonstrate the value of having insurance coverage generally, and Medicaid more specifically.

Study Methodology

This study used data from the MEPS survey. This ongoing national survey of households and individuals has been used by health services researchers for more than 20 years. It is administered by the Agency for Healthcare Quality and Research (AHQR). MEPS is the most complete source of public data on the cost and utilization of health care and health insurance coverage.

Across multiple measures of access to care and the provision of preventive services, AHIP researchers compared people having commercial or Medicaid health plans (ie. HMO, or health maintenance organization) versus no

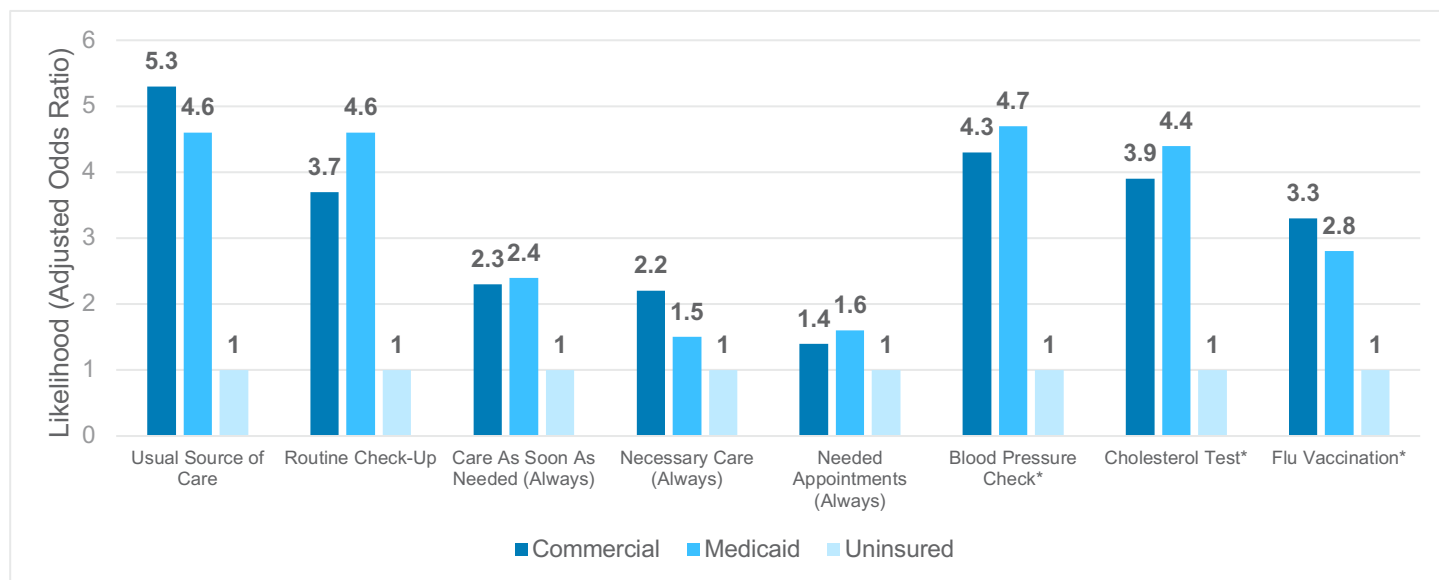
insurance coverage at all.

Results from this study are based on a sample of 38,678 individuals during the 2013-2015 timeframe. This final analytical sample was described using appropriate univariate statistics, and any associations between access to care and provision of preventive care services were initially assessed using Chi-Square Tests of Association.

Next, we constructed multivariate logistic regression models to further describe the relationship between insurance coverage status and the outcome variables of interest

The Value of Medicaid: Access to Care

Figure 1: Adults with Commercial or Medicaid Health Plan Coverage Have Better Access to Care and Are More Likely to Receive Preventive Care Services Than Uninsured Adults



* Preventive care services performed at any time in the preceding 12 months

These findings cannot be explained by underlying variations in demographics, overall health status, or geographic distributions of the sample of patients studied. See Appendix C for tabulated multivariate analysis results.

Children. As summarized in Figure 2, children having either commercial health plan or Medicaid health plan coverage, when compared to their uninsured peers, were significantly more likely to:

- Have a usual source of care.
- Have their blood pressure checked.
- Receive guidance from their health care provider with respect to healthy eating habits and regular exercise.
- Have a well-child/vaccination visit.

Children covered by Medicaid health plans were four-times more likely than uninsured children to have a usual source of care.

Simultaneously, the observation that children covered by a Medicaid health plan are more likely to have a usual source of care cannot be explained by variations in other influential covariates like race, ethnicity, age, gender, or census region of the country.

With respect to the provision of preventive care services, across four measures, Medicaid health plan children were two-to-three times more likely than uninsured children to receive these services, while controlling for variations in the same covariates noted above. Again, this offers strong evidence of a significant relationship between insurance coverage and access to care and preventive services, while controlling for variations in patient characteristics across the three insurance groups. See Appendix C for tabulated multivariate analysis results.






Raleigh Radiology Comments Wake Co MRI

Final Audit Report

2023-07-28

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