

WAKE
RADIOLOGY

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CON Section

02 AUG 2010 3:06

BODY IMAGING RADIOLOGY

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BODY/NUCLEAR MEDICINE

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Louis F. Posillico, MD

INTERVENTIONAL RADIOLOGY

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Michael D. Kwong, MD
Carroll C. Overton, MD
Thomas L. Presson Jr., MD
Philip C. Pretter, MD
Susan M. Weeks, MD
Andrew C. Wu, MD

MUSCULOSKELETAL RADIOLOGY

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Timothy J. Mihalovich, MD
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William J. Vanarthos, MD
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Russell C. Wilson, MD

MUSCULOSKELETAL/INTERVENTIONAL

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NEURORADIOLOGY

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Mark D. Marchand, MD
Bryan M. Peters, MD
Michael L. Ross, MD
Philip R. Saba, MD
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July 26, 2010

Gregory Yakaboski, Project Analyst
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
701 Barbour Drive
Raleigh, North Carolina 27626-0530

RE: Comments on Wake County Fixed MRI CON Applications

Dear Mr. Yakaboski:

Enclosed please find comments prepared by Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. regarding the competing CON applications for one fixed MRI scanner for Wake County, to meet the need identified in the *2010 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of the applications.

If you have any questions about the information presented here, please feel free to contact me at 919-787-7411. I look forward to seeing you at the public hearing.

Sincerely,

Robert E. Schaaf, M.D.
President

MEDICAL OFFICE LOCATIONS

RALEIGH
WR North Hills
WR Raleigh MRI
WR West Raleigh Imaging
WR West Raleigh Mammography
WR Northwest Raleigh
WR Pediatric Imaging
CARY
WR Diagnostic Imaging
WR Comprehensive Breast Services
WR Interventional Radiology
WR Cary MRI
WR PET-CT Services
Wake Radiology Oncology Services

CHAPEL HILL

WR Chapel Hill

GARNER

WR Garner

WAKE FOREST

WR Wake Forest

HOSPITAL LOCATIONS

WakeMed Raleigh
WakeMed Cary
WakeMed North
WakeMed Apex
WakeMed Clayton
WakeMed Brier Creek
Johnston Health Smithfield
Johnston Health Clayton
Maria Parham Medical Center
Central Regional Hospital-Raleigh
Central Regional Hospital-Butner

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All Wake Radiology locations are accredited by the American College of Radiology.



02 AUG 2010 3 : 06

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS
WAKE COUNTY FIXED MRI NEED DETERMINATION**

**Submitted by Wake Radiology Services, LLC &
Wake Radiology Diagnostic Imaging, Inc.
August 1, 2010**

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2010 State Medical Facilities Plan (SMFP)* for one fixed MRI scanner in Wake County. In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by the other applicants, and a discussion about whether the material in each application complies with the relevant review criteria, plans, and standards. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of a fixed MRI scanner program in Wake County.

Specifically, the CON Section, in making the decision, should consider several key issues, including the extent to which the proposed projects:

- (1) best improve geographic access to fixed MRI services in Wake County;
- (2) document adequate support from local referring physicians in the MRI service area;
- (3) reasonably demonstrate the need the population has for their proposed services;
- (4) represent a cost-effective alternative for developing a fixed MRI program; and
- (5) submitted complete applications with consistent information and realistic assumptions.

Geographic Access

The most important consideration in comparing the relative benefit of the alternative applications is improving geographic access to MRI services. Wake County is one of the largest and most populous counties in North Carolina. As a result, travel distances can be long, and traffic congestion is often significant. Thus, a proposed new fixed MRI service in Wake County should be targeted to most effectively increase convenient geographic access to full-time fixed MRI services.

The proposed Wake Radiology project will establish the first fixed MRI scanner in Garner. WRDI has provided mobile MRI services to the residents of Garner and surrounding communities for six years. As described in its application, WRDI identified the need for a fixed MRI scanner in Garner several years ago. In fact, Wake Radiology submitted two Certificate of Need (CON) applications for a Garner fixed MRI scanner during 2004 and 2005, respectively. As stated by the CON Project Analyst in the 2005 (most recent) Agency Findings for the Wake County fixed MRI scanner batch review:

“the proposal submitted by Raleigh MRI (Garner) is the most effective alternative with regard to improving geographic distribution of fixed MRI scanners in the Wake County MRI Service Area.”

With the 2005 approval of another fixed scanner in Raleigh, the identification of Garner as the most effective geographic alternative in Wake County is even clearer. The following table identifies the existing fixed MRI scanners in the Wake County MRI Service Area.

Wake County Fixed MRI Scanners by Location

PROVIDER	CITY/TOWN	# OF FIXED SCANNERS
Rex Hospital	Raleigh	2
Rex Healthcare of Cary	Cary	1
WakeMed Cary Hospital	Cary	1
WakeMed Raleigh Hospital	Raleigh	2
Raleigh MRI Center (Wake Radiology)	Raleigh	2
Duke Health Raleigh Hospital	Raleigh	1
Raleigh Neurology	Raleigh	1
Raleigh Radiology Cedarhurst	Raleigh	1
Raleigh Radiology ¹	Raleigh	1
Wake Radiology - Cary ²	Cary	1
Total		13

¹ Alliance HealthCare Services fixed MRI scanner per 3/07/08 declaratory ruling.

² Alliance HealthCare Services fixed MRI scanner per 10/05/09 declaratory ruling.

As shown in the previous table, thirteen fixed MRI scanners operate in the Wake County MRI Service Area. Ten fixed MRI scanners are located in Raleigh, and three fixed MRI scanners are located in Cary. There are currently no fixed MRI scanners located in Garner.

The proposed Duke Raleigh Hospital (DRH) scanner will be located in Raleigh, which, as the previous table demonstrates, is already well served with 10 fixed MRI scanners. Thus, the proposed DRH scanner provides no geographic access benefit, and is the least effective alternative. Therefore, a comparison of the other two proposed host municipalities (Garner and Holly Springs) is in order. As shown in the table below, Garner currently has a larger population than Holly Springs, and is projected to still have a larger population in 2014.

**Southeast Wake County
Municipality Population Projections**

	2009	2014
Garner town	24,023	27,666
Holly Springs town	18,063	22,763

Source: Claritas

Further, based on the data provided by each applicant, the population of the WRDI primary service area is much larger than that of Novant, as shown below.

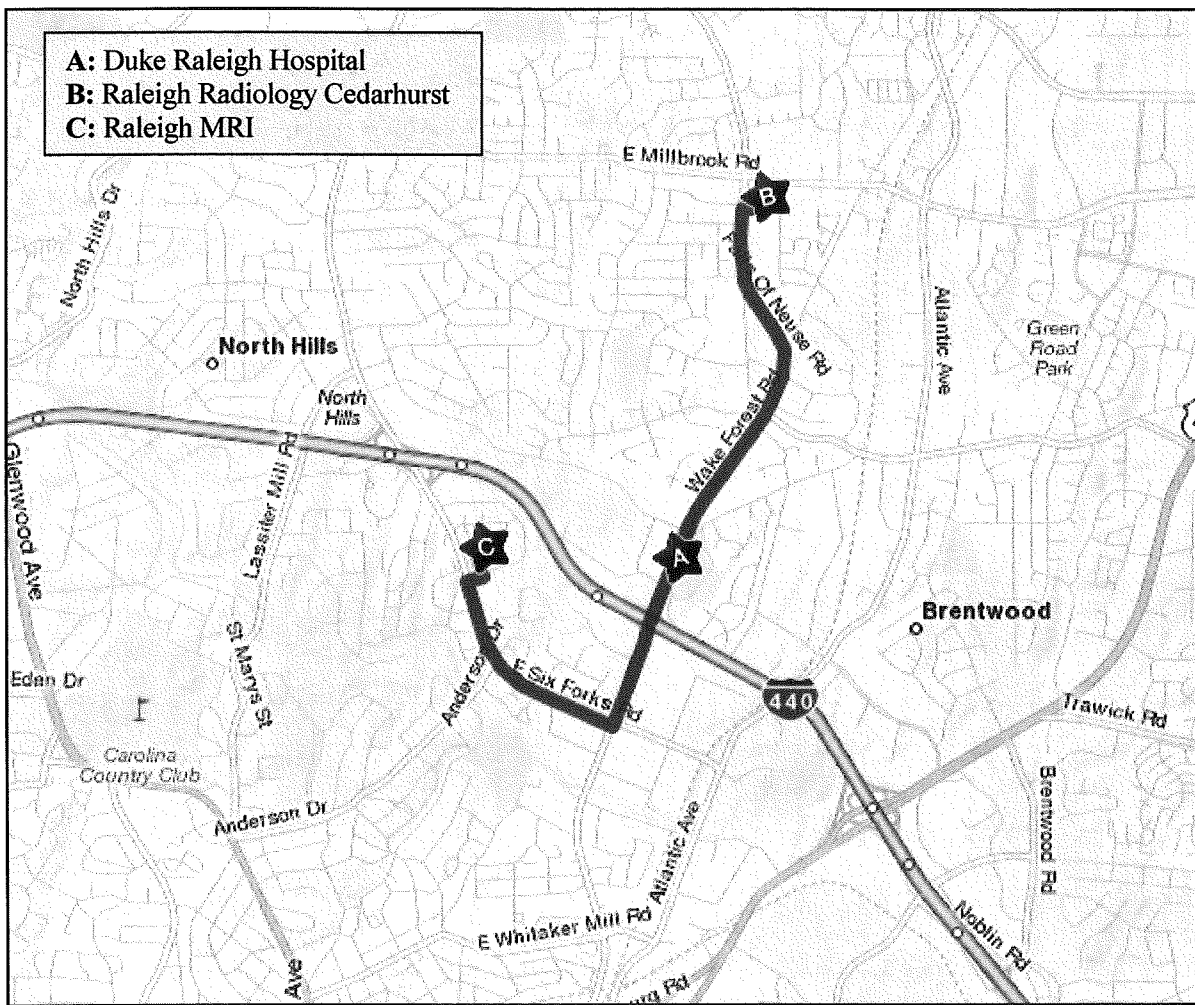
**Southeast Wake County
Primary Service Area Population Projections**

	2014
WRDI	341,407
Novant	126,367

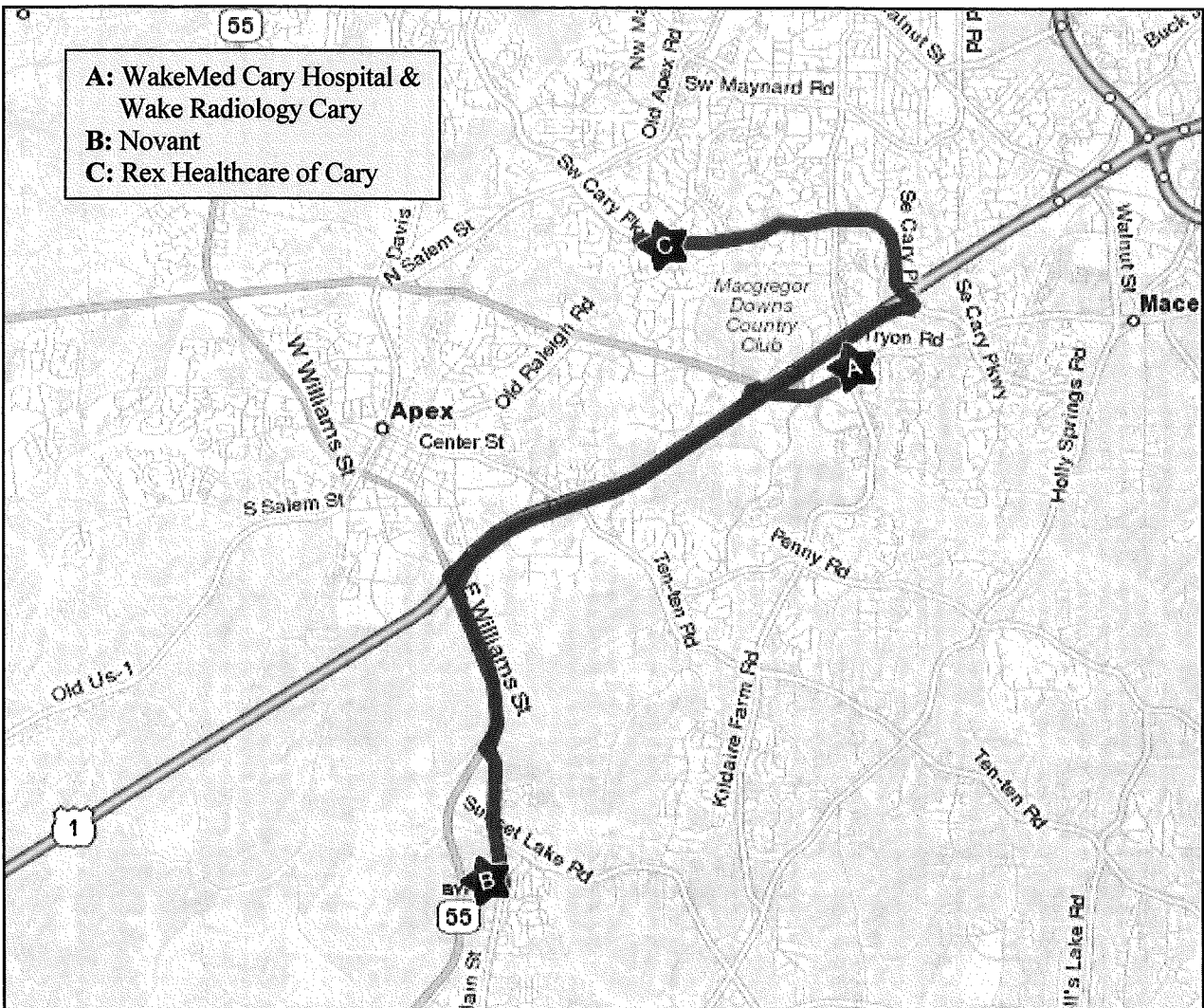
Source: CON Applications

Therefore, from the perspective of Wake County municipalities and the population targeted, the WRDI proposal is clearly the most effective alternative.

A further comparison of the proposed geographic locations of each applicant is useful in this review. DRH is currently an existing fixed MRI location, and thus the DRH proposal provides no benefit to Wake County residents from the perspective of geographic access. Further, the proposed DRH scanner (Location A on the map below) is also located just 1.6 miles (4 minutes) from the fixed MRI scanner located at Raleigh Radiology Cedarhurst (Location B on map), and just 2.0 miles (6 minutes) from the two fixed MRI scanners located at Raleigh MRI Center (Location C on map). These travel statistics are via MapQuest.com.



Similarly, as shown on the map below, Novant (Location B) is only 6.8 miles (10 minutes) from the existing fixed MRI scanners at both WakeMed Cary Hospital & Wake Radiology Cary (Location A), and 9.8 miles (13 minutes) from the fixed MRI scanner operating at Rex Healthcare of Cary (Location C).



By contrast, the proposed WRDI fixed MRI scanner location at 300 Health Park Drive in Garner is more than 10 miles from the fixed MRI scanners located at WakeMed Raleigh Hospital, 13 miles from the fixed scanner at DRH, 14 miles from the fixed MRI scanners at Raleigh MRI Center, 14 miles from the fixed MRI scanner at Raleigh Radiology Cedarhurst, 18 miles from the fixed MRI scanners at WakeMed Cary Hospital and WR Cary, and 20 miles from the fixed MRI scanner at Rex Healthcare of Cary. Clearly, the WRDI Garner proposal provides the greatest benefit to Wake County residents from the perspectives of 1) improved geographic access, and 2) reduced travel time to a fixed MRI scanner for geographically underserved residents.

In summary, based on the current locations of existing fixed MRI scanners in Wake County, Garner is underserved with respect to access to fixed MRI services. Garner is a larger municipality than Holly Springs. Furthermore, the proposed Garner fixed MRI scanner is located further from existing fixed MRI scanners than either the DRH or Novant proposals. And WRDI proposes to serve a much more populous primary service area than does Novant. Thus, the proposed fixed MRI scanner at WRGO is the most effective alternative for improving geographic access to fixed MRI services in Wake County.

Physician & Community Support

Another important factor to consider when evaluating the competing proposals is the extent to which the local community supports each proposed project; particularly the extent to which referring physicians will sustain the project. Physicians refer patients for MRI services, so physician support for an MRI scanner application is essential. This is particularly true for a proposed new provider, such as Novant. Notably, WRDI's application evidenced significantly more project support than did that of either DRH or Novant. Specifically, WRDI provided nearly 190 physician support letters, which speaks highly of the level of support Wake Radiology received from the local referral community for its proposed project.

By contrast, Novant received only 14 letters of support physicians. This raises a serious concern about the reasonableness of the Novant MRI volume projections, and of Novant's viability as an MRI provider. As the table on the following page shows, during Project Year 3 Novant projects to perform 4,661 unweighted MRI scans. However, the Novant application only documents 134 referrals. In short,

Novant has no basis upon which to assume that it will perform anywhere near the projected number of MRI scans.

Novant Projected MRI Scans

	Project Year 3
Projected Scans	4,661
Documented Referrals	134
% of Total	2.9%

Source: CON Application

In addition to ample physician support, WRDI received a letter of support from Stan Taylor, a Vice President at WakeMed. WakeMed also provides MRI services to the residents of Wake County. This letter documents the WakeMed belief that the WRDI project will enhance MRI services within the county. This is mainly due to the broad access to cost-effective care, and proven high quality care administered by Wake Radiology.

In summary, the lack of physician letters of support for the Novant proposal raises a significant question about the likelihood of MRI referrals, which are essential. This in turn casts doubt about the need for the Novant proposal, and thus about the financial viability of the project. By comparison, WRDI's proposal to acquire a fixed MRI scanner is well supported by the community, as evidenced by the many letters from physicians and community leaders documented in its CON application.

Capital & Start-up Costs

In its application, WRDI demonstrates that the cost, design, and means of construction, and equipment acquisition represent the most reasonable alternative of the three applications, and that the WRDI project will not unduly increase the costs of providing health services, or the costs and charges to the public of

providing health services. Please refer to the following table for project-related costs.

Project Costs

	WRDI	DRH	Novant
Capital Cost	\$1,819,102	\$4,952,700	\$2,099,869
Working Capital	N.A.	N.A.	\$345,515
Total	\$1,819,102	\$4,952,700	\$2,445,384
% Higher	--	172%	34%

Source: CON Applications

In the current economic climate, effective initiatives to contain unnecessary costs and expenditures are especially important to promote value in healthcare. Declining reimbursement rates and increased government regulations are increasingly placing downward pressure on healthcare providers to effectively do more with less. Thus, efficient management of project capital and start-up costs is crucial to providing value. WRDI projects by far the lowest project initiation costs among the competing applicants.

MRI Charges & Cost-Effectiveness

Average Charge per Procedure

Another issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of MRI services. In the current healthcare marketplace, where cost of care is a major concern with payors and the public, the projected average procedure charge is an important measure of consumer value. WRDI proposes very reasonable charges and costs. In fact, WRDI proposes the lowest average charge (technical component only) among the competing applicants.

Proposed Average Charge per Procedure*

WRDI**	Duke	NCDI - Holly Springs**
\$1,622	\$2,576	\$1,776
\$1,622	\$2,731	\$1,776
\$1,622	\$2,895	\$1,776

Source: CON Applications

*Reflects only technical charges

**Average technical charge per procedure was determined by calculating the average % professional fee for the top 20 MRI procedures for each applicant & then subtracting that amount from the average global charge per procedure for each applicant.

As noted in the table footer, WRDI and Novant both project global charges, while Duke Raleigh Hospital's charges include only technical fees. Therefore, a comparison of the technical fees is the only method of directly comparing the projected charges of each applicant.

One may also note that the DRH application projects a 6% annual increase in the average charge per MRI scan during the project. WRDI by contrast, proposes no increase in the MRI charge during the three project years. This demonstrates WRDI's commitment to competitive pricing and cost-effectiveness.

Cost effectiveness

The proposed WRDI project will reduce the cost of providing MRI services at WRGO. WRGO offers mobile MRI services via a mobile MRI contract with Alliance Imaging. As explained in its application, WRDI must pay Alliance a fixed amount per day of service for mobile MRI access at WRGO. This fee is very expensive compared to the cost of offering fixed MRI services at WRGO on a full-time basis. In fact, as shown in its financial proformas, WRDI projects to reduce its FY2009 cost per scan by 51%, to \$369/scan in FY2014. With better control of its costs, WRDI will be in a stronger position to ensure a competitive charge structure at WRGO now and in the future, which will ultimately benefit patients.

As stated in the CON Review Criteria, applicants are expected to demonstrate a positive effect on competition in the Service Area. WRDI's proposal positively

encourages more effective competition by offering cost-effective charges. The proposed fixed MRI scanner by WRDI represents a cost-effective alternative for the residents of Wake County, based on a comparison of charges and cost effectiveness.

Medically Underserved Access

As documented in its application, if WRDI is awarded a fixed MRI scanner, WRDI has offered to partner with Project Access of Wake County to provide one free MRI scan each week to local patients who are uninsured or underinsured. Project Access is a physician-led community effort that has provided health care for low-income and uninsured Wake County residents since 2000. The prospective agreement will provide 52 charitable scans each year in the local community.

WRDI takes pride in providing care to persons covered by government insurance or depending upon charity care. WRDI provides charity care, and a projected MRI Medicare and Medicaid payor mix above 29%. As a for-profit healthcare entity with no legal obligation to provide charity care, WRDI invests considerable resources in extending healthcare services to the medically underserved. As shown on the following table, WRDI projects to provide greater Medicare & Medicaid access than Novant, the other non-hospital applicant.

Projected MRI Payor Mix: Medicare & Medicaid

Payor Mix Yr 2	WRDI	Novant
Medicare	26.4%	15.2%
Medicaid	2.7%	4.8%
Total	29.1%	20.0%

Source: CON Applications

WRDI is committed to providing the medically underserved with quality healthcare services. WRDI also acknowledges that DRH by nature, as a not-for-profit hospital provider, also provides extensive care to the medically underserved. Because of the distinctly different tax statuses of WRDI and DRH, the two entities are not directly comparable in terms of expanding access to the local medically underserved population.

Specific comments regarding the Duke Raleigh Hospital application

- DRH utilizes a “black box methodology” to justify its utilization projections. On page 29 of its application, DRH references projections provided by Sg2. However, nowhere in the application does DRH provide these projections, nor does it document the methodology that Sg2 uses to develop its projections. Since DRH claims these projections as a reason for its need, this omission results in a material deficiency of the DRH application.
- The DRH income statement appears to significantly underestimate the expenses associated with offering MRI services. Specifically, on Form C for project year 3 DRH estimates that its total indirect expenses (excluding equipment maintenance and equipment depreciation) is just \$10,637. By comparison, WRDI’s comparable indirect expense total is \$357,932, and Novant’s comparable indirect expense total is \$608,415.
- DRH does not reflect adequate staffing for the proposed MRI project. Specifically, Table VII.2 does not specify administrative or support staff, both of which are necessary to operate a full-time fixed MRI scanner. Therefore, DRH’s application is non-conforming to Review Criterion 7.
- The staffing expense projected by DRH on Form C of its proformas does not match the staffing expense listed on Table VII.1. The difference between the two exceeds \$100,000, and therefore calls into question the accuracy of the DRH financial projections.
- DRH does not document the rationale for its projected increased Medicaid payor mix. On page 50 of its application, DRH shows that its FY2009 Medicaid payor mix for MRI services was 5.8%. On page 51 DRH then projects its MRI Medicaid payor mix will be 8.6%, with no explanation for the 48% increase, other than to state “the Medicaid percentage will also increase”.
- On page 28 of its application, DRH justifies its utilization projections based partially on a claim that it will hire 31 additional physicians by the third project year. However, DRH provides no documentation to validate this aggressive claim. Further, DRH provides no evidence that any of these physicians would refer MRI patients, or how many referrals would be proffered.

- DRH's annual practical capacity is sufficient to satisfy its current and future needs. Specifically, on page 8 of its CON application DRH states that normal MRI hours of operation are currently 106.5 hours per week. Based on a standard throughput estimate of one patient per 30 minutes, DRH's estimated actual MRI operating capacity is:

Duke Raleigh Hospital
Estimated existing and approved MRI Capacity

Days Per Week	Hours Per Week				Procedures/ Hour	Total Procedure Capacity
	Open	Total	Clean Up	Available		
7	M-F 16.5 hours/day Sat-Sun 12 hours/day	106.5	---	106.5	2.0	11,076

Total Available Hours (TAH) =
 =52 weeks X 106.5 hours/week =5,538

Total Capacity (TC) =
 TAH X Procedures/Hour = 5,538 X 2.0 Procedures/Hour = 11,076

According to this calculation, in FY2009 DRH's MRI scanner operated at approximately 55% capacity (6,070/11,706). DRH has more than enough capacity to handle its projected volumes for the next several years. Thus, DRH's need for an additional fixed MRI scanner is not justified, and its proposal is not the most effective alternative.

- DRH indicates that it is currently contracting with a mobile MRI provider for services, and that it will replace this service with the proposed fixed

scanner. However, DRH does not disclose when its contract with the mobile MRI provider expires. Indeed, if the contract continues during the initial three project years, then DRH has not included as expenses any fees that it is contractually obligated to pay to the mobile provider.

- An analysis of projected MRI reimbursement shows WRDI's proposal to be a more effective alternative for Wake County residents than that of DRH. As shown in the table below, WRDI projects a lower average reimbursement than DRH. Notably, the WRDI average reimbursement per MRI procedure is declining each year of the project, while DRH projects its reimbursement to increase each project year. This is an actual, tangible benefit to the residents of Wake County, in that WRDI's charges reflect a focus on competitive and reasonable pricing for high quality MRI services for residents of the Wake County MRI Service Area.

Proposed Average Reimbursement per Procedure*

WRDI**	DRH
\$831	\$821
\$827	\$839
\$822	\$862

Source: CON Applications

*Reflects only technical charges

**Average technical charge per procedure was determined by calculating the average % professional fee for the top 20 MRI procedures & then subtracting that amount from the average global charge per procedure.

Specific comments regarding the Novant application

- Novant does not adequately document that sufficient utilization of its services will exist in the future in order to satisfy the MRI performance standard. Several fundamental flaws in their methodology make Novant's projected volumes unreasonable.

First, Novant's market share estimations are unrealistic. Novant includes a table in its application which projects market share by census tract. In several of these tracts, Novant projects its market share to be 50% during the initial project year, and nearly 60% by the third year. For a provider that does not currently offer healthcare services in Wake County, this is unreasonable. Novant provides no quantitative or qualitative evidence of the likelihood of a need MRI provider obtaining 50% market share during the first project year. Novant's projection is even more unrealistic when one considers that the proposed fixed MRI scanner would be the 14th in operation in Wake County. And this doesn't even place into consideration the many existing mobile MRI scanners in Wake County. As justification for these figures, Novant claims that its primary care physician offices are "planned for development" in Holly Springs, and that Novant Medical Group general surgeons are "exploring an office location in Holly Springs". Conjecture based on undefined future plans is not a basis for making realistic market share projections.

Second, Novant assumes that 5% of total projected utilization during each project year will be from other areas or in-migration. As the basis for this claim, Novant cites the experience of "other MedQuest facilities in North Carolina". However, Novant does not identify these other MedQuest facilities, nor does it provide any data to substantiate the comparison between these unnamed facilities and the proposed Holly Springs facility. Further, Novant projects 2% of its patients to come from "other" counties. Novant then lists the following counties as the source of these patients: Durham, Orange, Sampson, Duplin, Nash, Craven, Wayne, Vance, Warren, and Person counties. Novant provides no analysis of the need for residents of these counties to travel great distances to Holly Springs to obtain an MRI scan. By stark contrast, Novant projects to locate its MRI scanner approximately eight miles from the Harnett County line, yet projects no Harnett County residents in its patient origin.

Another flaw in the Novant need methodology is the major discrepancy between the MRI volume Novant projects, and the volume of patients physicians expect to refer in the letters of support submitted with the Novant application. As previously documented in these comments, for the third year of the project, those few physicians voicing support for Novant expect to provide only 134 referrals. Yet Novant is projecting 4,661 unweighted scans for that year. This is an overwhelming 3,378 % discrepancy. On page 63 of its application, Novant specifically claims that letters of support from local providers is a factor justifying the Novant market share percentages used in the Novant methodology. In short, Novant clearly fails to document sufficient referral support for their volume projections. By contrast, WRDI is projecting 4,444 unweighted scans for the third project year, which their referring physician letters of support easily justify with their projected referral volumes.

- A comparison of projected operating costs shows that WRDI proposes a competitive cost structure. It is important to note, however, that as discussed previously in these comments, the volume projections of Novant are unrealistically high, and based on unreasonable assumptions and a dearth of physician referral documentation. Therefore, Novant’s projected average cost per scan reflected on the following table is not reliable, and likely would be much higher.

Projected Average Cost per MRI Procedure

Provider	WRDI	Novant
Project Year 3	\$369	\$319

Source: CON applications

- Novant’s proposed NCDI-Holly Springs is a new proposed facility. Novant states on page 100 of its application that its projected payor mix “is based on the historical payor mix for MedQuest sites in the region”. However, Novant does not provide any further data or explanation to justify why this is a reasonable basis for its Holly Springs payor mix projection. The Novant application does not appear to include any analysis of what types of patients in Wake County obtain MRI services. Further, Novant does not clearly document how it arrives at the estimate of 5.6% of its MRI volume that will be provided on a charity care basis.

- Novant claims that it will provide over 100 free MRI procedures annually via a partnership with Project Access. However, Novant's application does not include any documentation from Project Access. By contrast, the WRDI application includes a letter from the Project Access Program Manager to Wake Radiology confirming its willingness to partner with WRDI.
- The traffic study Novant included in its application is nearly two years old. Further, it represents a measure of travel distances and times that are not reflective of the proposed Novant MRI location. Specifically, the study purports to measure travel times and distances from both the Holly Springs and Fuquay-Varina town halls. According to a map, Novant's proposed fixed MRI scanner will be located well north of both of these town hall facilities. Thus, the traffic study is of no value in evaluating the Novant proposal.
- Novant has not purchased or optioned the physical site, and thus does not have control of a site for the proposed MRI scanner. Both the other applicants propose to develop their fixed MRI scanner at existing facilities. Thus, there is a likelihood that Novant will not actually develop its proposed service at the identified site, and will have to seek a declaratory ruling for a new site.
- As previously stated, both WRDI and Novant received letters of support from local health care practitioners. However, WRDI received over 13 times as many physician letters of support. Novant only received 14 letters from physicians. Further, the referral estimates from the Novant letters total only 134 referrals in the third project year, less than 3% of the Novant volume projection.
- Novant is not an existing provider in Wake County, and would incur the expenses of a new provider. By comparison, WRDI is a familiar, existing provider in Wake County. WRDI has relationships with physicians in the area and is experienced in treating patients from the service area. As a new provider, Novant would pay significantly more in capital and start-up costs to operate the proposed fixed MRI scanner. Novant's combined capital and start-up costs total \$2,445,384, which is 34% higher than the WRDI project initiation cost.