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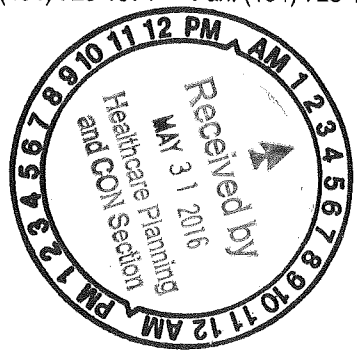
May 31, 2016



Via Hand Delivery
Ms. Gloria Hale, Project Analyst
Ms. Fatima Wilson, Co-Signer
Health Planning and Certificate of Need Section
809 Ruggles Drive
Raleigh, NC 27603

Re: Written Comment by Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. regarding Raleigh Radiology, LLC's Certificate of Need application to acquire a fixed MRI scanner in Wake County, North Carolina (Project I.D. # J-011159-16)

Dear Ms. Hale and Ms. Wilson:

Enclosed please find comments by Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. (collectively "Wake Radiology") regarding the competing Certificate of Need ("CON") application submitted by Raleigh Radiology, LLC ("Raleigh Radiology") to acquire one fixed MRI scanner in Wake County. Three CON applications were filed to meet the need identified in the 2016 State Medical Facilities Plan for one fixed MRI scanner for Wake County – Raleigh Radiology's application, Wake Radiology's application (Project I.D. # J-011172-16) and Duke University Health System, Inc. ("DUHS") (Project I.D. # J-011167-16). Wake Radiology is also filing separate comments regarding DUHS' application. These comments are submitted in accordance with N.C. Gen. Stat. § 131E-185(a1)(1).

Thank you for your consideration of this information.

Sincerely,

Kathryn MT Platt

Kathryn MT Platt
President

COMMENTS REGARDING RALEIGH RADIOLOGY, LLC'S CERTIFICATE OF NEED APPLICATION TO ACQUIRE A FIXED MRI SCANNER
Project I.D. # J-011159-16

Submitted by Wake Radiology Services, LLC & Wake Radiology Diagnostic Imaging, Inc.
May 31, 2016

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the 2016 State Medical Facilities Plan (SMFP) for one fixed MRI scanner in Wake County. The applications were submitted by Duke University Health System, Inc. ("DUHS") (Project I.D. # J-011167-16), Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. (collectively "Wake Radiology") (Project I.D. # J-011172-16), and Raleigh Radiology, LLC ("Raleigh Radiology") (Project I.D. # J-011159-16).

In accordance with N.C.G.S. § 131E-185(a1)(1), this document includes comments relating to the Raleigh Radiology application. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of a fixed MRI scanner in Wake County.

Specific Comments regarding the Raleigh Radiology Application

The application submitted by Raleigh Radiology must be denied because it does not conform to the Statutory Review Criteria and MRI Criteria and Standards, including the performance standards, and does not promote the three basic principles of the SMFP. Raleigh Radiology's project is not cost-effective and does not meaningfully increase access to MRI services in Wake County or any other surrounding county. The project feasibility is questionable given that the applicant does not account for significant expenses associated with the project.

By contrast, the application filed by Wake Radiology to acquire a fixed 1.5T MRI scanner to be located in the Wake Forest area near its existing Wake Forest Office provided all required information and will increase cost-effectiveness, access and quality of care in Wake County. Comparatively, Wake Radiology's application is the superior application among all the applicants based on a number of comparative factors, including project costs, financial accessibility, and overall reasonability of the projections. Wake Radiology's application should be approved and Raleigh Radiology's application should be denied.

The following discussion identifies specific failures of Raleigh Radiology's application to comply with Statutory Review Criteria located in N.C. Gen. Stat. § 131E-183(a).

Criterion 1: ***The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health***

service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

Raleigh Radiology's application is inconsistent with the basic principles of the SMFP under Policy GEN 3. Raleigh Radiology does not identify a population in need and demonstrate that it will meet that need simply because Raleigh Radiology is not adding a new MRI unit to meet the need in the 2016 SMFP as discussed above. Raleigh Radiology is simply replacing an existing MRI unit owned by Alliance imaging with a new MRI unit to serve exactly the same patient population. At the end of Raleigh Radiology's project, it will continue operate one MRI unit at its existing imaging center in Cary and the Alliance Imaging leased MRI will be removed from the inventory of MRI units in Wake County. There is no net increase in the inventory of Wake County MRI units as described.

As described above, Raleigh Radiology submitted comments and petitioned the Technology and Equipment Committee for the inclusion of the need for one new MRI unit in Wake County in the 2016 SMFP. In support of its petition Raleigh Radiology noted the following:

- Rapid population growth in Wake County that will drive demand for more MRI services;
- Growth in demand for MRI services at its centers and in Wake County;
- Raleigh Radiology's limitation in offering MRI services through its high priced relationship with Alliance;
- Raleigh Radiology's own high level of utilization of its existing site locations exceeding capacity thresholds;
- Raleigh Radiology's need to operate extended hours to meet demand at its center; and
- Declining reimbursement and high fixed cost of operating an MRI;

Raleigh Radiology succeeded in convincing the committee to adjust the SMFP recognizing the need for one additional MRI in Wake County.

In determining the need for including of the Wake County need in the SMFP, the Agency Report finds the following factors that support the inclusion:

- Wake county's average procedures per scanner has consistently been over 4,000 every year for the past ten years;
- The annual number of scans has consistently risen over the last ten years with a CAGR of 5.33 percent; and
- One more year of growth at the same weight would result in an average weighted equivalent scans above the required threshold average per scanner.

It is important to note that the Agency Report focused on inclusion of the need for an MRI unit in Wake County based on growth in utilization of MRIs in the County and the area-wide need

and not the specific circumstances of a single provider as argued by Raleigh Radiology. The inclusion of a need for a new fixed MRI in Wake County in the SMFP was intended to meet the growth in demand and the overall county need and not solve an operational or financial issues for any particular provider.

In response to the need in the SMFP, Raleigh Radiology filed an application for a project that will not meet the very need it identified and will not meet the need in the SMFP. As will be discussed in detail, Raleigh Radiology proposes to replace an existing MRI, so that it can have full financial control of the unit. Raleigh Radiology proposed to replace the Alliance Imaging owned unit at its Raleigh Radiology-Cary location with another MRI. There is no meaningful increase in capacity of MRI services associated with this project. This is not a health planning need that is being met nor does the project serve an overall Wake County need for an additional MRI unit.

Raleigh Radiology's application should be found non-conforming with Criterion 1 based on the fact that it will not add an additional new MRI unit to Wake County to meet the need in the SMFP that was driven by the Agency Staff's finding that continuing growth in demand for MRI services will result in a need for an additional unit in the County.

Raleigh Radiology's proposed project is inconsistent with the basic principles of the SMFP under Policy GEN 3. The proposal is not cost-effective. Raleigh Radiology's capital costs are very high at almost $3 million, and Raleigh Radiology has not adequately demonstrated the reasonability of these capital cost for the project, including the added cost for a 3T MRI unit, which it has not demonstrated to be needed for the population it proposes to serve. Raleigh Radiology's proposal also fails to enhance access for all Wake County residents. Raleigh Radiology's project is essentially a replacement of an existing MRI scanner at an existing Cary location, which is already well served by Raleigh Radiology through a leased MRI scanner. Raleigh Radiology's project will also not increase access to financially underserved patients. Raleigh Radiology has historically provided just 2% of MRI services to self pay/indigent/charity care and Medicaid patients combined. Raleigh Radiology projects increases in provision of care to these underserved groups but its projections are not supported by its historical experience and not based on reasonable assumptions.

For all of these reasons, Raleigh Radiology's application should be found non-conforming with Criterion 1.

MRI Criteria and Standards
Section .2700-Criteria and Standards for Magnetic Resonance Imaging Scanner
10A NCAC 14C .2703: Performance Standards

As will be discussed in greater detail below, Raleigh Radiology's projected utilization, while meeting the minimum volume required in 10A NCAC 14C.2703(3) are unrealistically high and cannot be achieved. The projected volume would make Raleigh Radiology the second most highly utilized freestanding, fixed MRI unit in the State. The Raleigh Radiology application did not adequately demonstrate that Raleigh Radiology can achieve its projected utilization with the hours of operation and staffing it has proposed.

Criterion 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.***

Raleigh Radiology Does Not Meet the Need in Wake County.

As discussed above, Raleigh Radiology's project does not meet the need in the SMFP for a new MRI to serve Wake County. Further, Raleigh Radiology does not identify any base of patients with need for an MRI services for which it will meet the need. Raleigh Radiology will simply swap an existing admittedly clinically appropriate MRI unit with a new more expensive MRI unit without meaningfully increasing access.

Raleigh Radiology Does Not Meaningfully Increase Capacity

Raleigh Radiology's proposal does not add any meaningful capacity to Wake County despite its projected operating hours. Raleigh Radiology asserts that the new MRI unit will have more capacity; however these arguments are simply not supported or meaningful to the availability of MRI services in Wake County. Raleigh Radiology itself claims that Wake County needs additional capacity but their plan does not add any meaningful capacity, as will be discussed below.

On page 36 of its application, Raleigh Radiology concurs with the Agency that there will be a deficit by 2019 of 4,681 weighted equivalent MRI scans. Raleigh Radiology claims that its new unit will have a capacity of 2,625 weighted equivalent scans more than the existing Alliance unit at Raleigh Radiology-Cary has now. (Raleigh Radiology application, p. 37) Raleigh Radiology's increase in capacity is not enough to meet the growth in MRI demand identified in the Agency Report and supported by Raleigh Radiology.

2019 Deficit of Wake County Scan Capacity (p. 36)	4,681
Projected Incremental Capacity Proposed by Raleigh Radiology (page 37)	2,625

Demand Not Met by Raleigh Radiology's Project	2,056

Raleigh Radiology suggests it will add 8 hours of operation for the Raleigh Radiology-Cary center on Sunday to expand capacity. It suggests that this 8-hour day cannot be accommodated by Alliance without exorbitant cost, but Raleigh Radiology does not provide any figures to support this claim. It is highly unlikely that Alliance's lease costs are substantially greater than the additional costs of this project as discussed below. More importantly, adding a few hours of service to an existing site that already operates 84 hours per week will not meaningfully increase capacity. Increasing hours of operation begins to have diminishing returns after a certain point. There are a limited number of patients that would want to be scanned on Sunday and certainly it is unlikely to fill 8 hours of scheduled time. Likewise, operating 14 hours per day, as Raleigh Radiology is currently doing, also adds limited capacity as a limited number of patients will want to be scanned in the very early morning or late into the evening. Raleigh Radiology's claims of increased capacity are not realistic and not supported by reasonable assumptions or data.

As will be discussed below, Raleigh Radiology has not demonstrated the clinical need for or the cost effectiveness of the proposed 3T MRI unit. In addition, the reduced scan time of the proposed unit does not materially increase the available capacity of MRI services. Given that additional hours of operation beyond a certain point result in diminishing increases in capacity, it is important to identify whether there is any meaningful impact of the new scanner on scan time. Raleigh Radiology suggests that the new MRI will reduce scan times by 7 minutes. (Raleigh Radiology application, p. 50) This miniscule increase does little to offset demand as shown below.

Current Hours of Operation	4,270
New MRI Scan Time	.50 hours
Efficiency Factor	86%
Proposed Capacity	7,344
Existing Capacity	5,955
Increase in Capacity	1,398

Raleigh Radiology's projected capacity of 8,046 MRI scans or 8,496 weighted MRI scans is unrealistic and not reasonably supported, given the diminishing returns of additional Sunday hours of operation and long extended days. Raleigh Radiology's projected capacity is 24% higher than the capacity for fixed MRI units of 6,864 defined in the Criteria and Standards for MRI Scanners.

In addition to greatly exceeding the fixed MRI capacity definition in the Criteria and Standards, Raleigh Radiology's projected capacity is also unreasonable compared to the operating experience of the existing freestanding fixed MRI units in Wake County. To demonstrate the unrealistic nature of Raleigh Radiology's projection, the 2016 SMFP shows that only one

freestanding-fixed MRI unit in the entire State of North Carolina is operating at over 8,046 scans per year. Only two freestanding-fixed MRI units performed over 6,000 MRI scans per year.

Raleigh Radiology's Proposed MRI Unit Does Not Meet the Demand Identified.

On page 66 of Raleigh Radiology application, it suggests that Wake County will need increased capacity to perform 6,596 additional scans in 2020. This is based on a projected growth in demand of 9,576 adjusted equivalent scans between 2015 and 2020. Raleigh Radiology similarly argues that patients from surrounding counties using MRI units in Wake County will add another 7,735 MRI procedures to the demand for Wake County MRI capacity. (Raleigh Radiology application, p. 44) However, its own calculations on page 50 show that its proposed MRI unit will only add 2,625 procedures in terms of capacity.

Adding a new unit to the County, as opposed to essentially replacing an existing units, would be a far better use of health care capital and operating costs compared to a minimal increase in capacity for the high incremental cost of Raleigh Radiology's project. Based on Raleigh Radiology's own projections, a new fixed MRI unit is needed in the County and the replacement of an existing unit will only marginally meet any need identified by Raleigh Radiology. Stated differently, Raleigh Radiology has failed to address a need for the population it proposes.

Raleigh Radiology will Not Increase Geographic Access

Because Raleigh Radiology is proposing to replace an existing MRI scanner at the same location as the current scanner in Cary, the proposed project will not have increase geographic access of MRI services in Wake County. In contrast, the Wake Forest area of Wake County is rapidly growing and does not have access to a fixed MRI unit. There are already several existing fixed MRI units in Cary and Raleigh Radiology simply proposes to replace one maintaining the same geographic distribution of MRI units in Wake County.

Raleigh Radiology Did Not Adequately Demonstrate Its Project is Accessible to Underserved Populations.

As will be discussed in more detail below, Raleigh Radiology's historical experience in providing MRI services in the exact same location proposed in this application does not demonstrate accessibility to underserved populations. In the most recent year reported, Raleigh Radiology provided just 2% combined services to self pay/indigent/charity and Medicaid patients. This volume is very small and woefully inadequate to meet the needs of this population. In addition, Raleigh Radiology provided just 23% of its services to Medicare patients, which is also low given that senior age 65 and older have by far the highest rate of MRI use. Raleigh Radiology projects increasing levels of self pay/indigent/charity, Medicaid and Medicare provision in its application but Raleigh does not explain how it will increase these

levels of service operationally and why its historical level of access is not the best measure of its future accessibility.

Raleigh Radiology Has Not Demonstrated the Need for a 3T MRI Unit.

Raleigh Radiology fails to show any support in its proposed service area for a 3T scanner, which is more complex than Raleigh Radiology's existing 1.5T scanner and more expensive to purchase and maintain. Raleigh Radiology has not demonstrated any specific demand for a 3T unit nor any clinical need for a 3T unit. None of the physician and referring provider letters of support in Raleigh Radiology's application indicate that there is a need for a 3T MRI unit. The proposed 3T unit is not even mentioned.

Simply because the proposed service area allegedly does not have a 3T scanner is no reason to award one to Raleigh Radiology. Raleigh Radiology's support letters clearly show that support for this project is coming from Raleigh Radiology's existing referral base, which has been referring to Raleigh Radiology's 1.5T scanner. There is nothing to show that this referral base needs the capabilities of a 3T scanner as compared to a 1.5T scanner. Raleigh Radiology assumes that the procedure mix will remain constant. As the applicant, Raleigh Radiology has the burden of demonstrating a need for a 3T scanner, which it is failed to do so.

On page 77 of Raleigh Radiology's application, it specifically states that ***"The current Alliance scanner at RRCary is a 1.5T, Seimens Espree Scanner. The scanner meets the standards of the RRCary physicians."*** Not only do referring physicians and other providers fail to show a demand or need for 3T technology, Raleigh Radiology's own physicians are perfectly satisfied with the quality of the existing 1.5T unit. There are actually drawbacks to 3T technology. For instance, many patients find the higher Tesla strength to cause vertigo and nausea.

A detailed comparison of the safety, technical, and clinical aspects of 1.5T to 3.0T MRI units as wells as a cost comparison was conducted in 2011 by the Canadian Agency for Drugs and Technologies in Health.[1] This report demonstrates that there are as many disadvantages as advantages to a 3T MRI scanner compared to and 1.5T MRI scanner. The cost comparison demonstrates that the 3T MRI units are significantly more expensive than 1.5T MRI units. Given the lack of clear advantages, the higher costs is difficult to justify. Most importantly, Raleigh Radiology's application did not document the need for a 3T MRI unit clinically or otherwise.

[1] Wood R, Bassett K, Foerster V, et al., Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2011 May.

Raleigh Radiology's Proposal is Not Cost Effective As Suggested.

Raleigh Radiology's main argument in support of the need for its proposed project is the suggestion that the new 3T MRI at a project cost of almost $3 million is more cost effective than the continued lease of the existing, clinically appropriate, 1.5T MRI from Alliance at the same location. Raleigh Radiology's own financial schedules and assumptions clearly document that there is no cost savings associated with the proposed project as shown below. The assumptions to Form B shows that the annual indirect expense associated with the Alliance MRI lease is $1,121,764 and this fee appears to be a flat annual rate without escalation or inflation. When the incremental costs associated with the proposed new MRI unit (B through H) are compared to the lease rate for the Alliance MRI unit (A), Raleigh Radiology will actually pay more to own and operate the proposed new MRI unit than the existing Alliance lease.

Comparison on MRI Operating Costs

A	**Alliance Annual Contract**	**$**	**1,121,764**
	Raleigh Radiology Direct Cost		
B	Staff	$	326,786
C	Benefits	$	88,232
D	Equipment Maintenance	$	110,987
E	Interest	$	118,559
F	Taxes	$	26,457
G	Professional Fees	$	118,559
H	Depreciation	$	417,071
I	**Total Cost to Raleigh Radiology**	**$**	**1,206,651**
J	***Annual Savings (Loss)***	***$***	***(84,887)***

A - Assumptions to Form C
B - Form C - 2018
C - Assumptions to Form C (27%)
D - Assumptions to Form C
E - Assumptions to Form C
F - Form C - 2018 less 2016
G - Form C - 2018 less 2016
H - Assumptions to Form C
I - Sum of incremental costs of new MRI unit
J - I less A

Based on Raleigh Radiology's actual projections, there are no cost saving associated with this project as suggested. In fact, Raleigh Radiology will be paying more on a replacement MRI unit that will add minimal additional capacity and will not meet the growing demand for MRI services in Wake County.

Unreliability of Raleigh Radiology's Support Letters.

Raleigh Radiology's support letters are unreliable and should be disregarded. In addition, they do not provide adequate support of its utilization projections. Raleigh Radiology's volume projections are not supported by and are inconsistent with the physician support letters.

On page 104, Raleigh Radiology discusses the letters of support it received. Raleigh Radiology lists in Exhibit 26 to its application a number of physicians whose historical referrals it is relying upon to project future volume, but who did not provide any letter of support for this project. Without a letter of support, those physicians' historical referrals should not be interpreted as an indication of future referrals.

Some of the support letters are unreliable in that they rely on projected referrals that are unreasonable in light of the historical referrals. For instance, one of the letters from Melissa Korzi, a Physician's Assistant at Crescent Family Practice, provides that she referred 12 patients to Raleigh Radiology Cary for MRI services in the 12 months ending November 2015. However, the letter next states that Ms. Korzi expects "to refer hundreds of patients for MRI to Raleigh Radiology Cary each year." Crescent Family Practice is a small family medicine practice and one of its physicians, Joseph W. Bruckert, MD, did not even provide a letter of support for Raleigh Radiology's project. In addition, Crescent Family Practice's other physician, Corey Musselman, MD, historically referred 27 patients to Raleigh Radiology's Cary MRI, and projected to refer 35 patients on an annual basis. It is simply unreasonable to think that a Physician's Assistant at a small family medicine practice would refer hundreds of patients to one MRI scanner each year. It is unreasonable to support utilization projections based on such overuse of MRI services.

Another example of an unreliable support letter is that of the letter from David Adams, MD. The support letter of Dr. Adams states that he referred 12 patients to Raleigh Radiology Cary for MRI services in the 12 months ending November 2015. It goes on to state that he expects to "refer approximately 100+ patients for MRI to Raleigh Radiology Cary each year." Dr. Adams is the only physician in a medical practice named "Office of Dr. David Adams." Based upon a review of his support letter and his website, there is nothing to justify why he would be changing his referral pattern from 12 patients annually to 100 plus. Again, it is unreasonable to support utilization projections based on such overuse of MRI services.

Raleigh Radiology's support letters speak only to Wake County, not the other counties in its proposed service area, which consist of Chatham, Durham, Harnett, Johnston and Lee Counties. Raleigh Radiology projects that 11.3% of its patients will come from these counties. In addition, Raleigh Radiology projects that 4.4% of its patients will come from areas other than Wake, Chatham, Durham, Harnett, Johnston and Lee Counties. However, Raleigh Radiology's application provides no support for these other areas, except for providing its 2015 patient origin for MRI services at Raleigh Radiology. The support letters mention no physicians practicing in

any county other than Wake County. The support letters also reference Raleigh Radiology as providing MRI services in Wake County for many years, but fail to mention that Raleigh Radiology has provided MRI services in any other county. The support letter are yet another example of Raleigh Radiology's intent to perform MRI services in the same manner as it has historically on the Alliance MRI scanner and runs counter to Raleigh Radiology needing a 3T scanner to meet such need.

Raleigh Radiology's application shows it is seeking to provide fixed MRI services to its existing patient base because it wants to get out of a contract with Alliance. It is not the intent of any of the Criteria, and in particular Criterion 3, 6 and 18a, for conformity to be based on the need to cancel an existing contract. While showing support for its project primarily from existing referrals to its 1.5T scanner and ignoring the many existing fixed MRI scanners nearby to Raleigh Radiology's proposed location, Raleigh Radiology is clearly articulating a need primarily based on getting out of its relationship with Alliance. For the numerous reasons above, Raleigh Radiology's application should be found non-conforming with Criterion 3.

Criterion 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.***

The Raleigh Radiology application fails to demonstrate that the least costly or most effective alternative has been proposed, and otherwise demonstrate conformity with Criterion 4. The replacement MRI proposed by Raleigh Radiology add minimal additional MRI capacity to meet the growth in demand for MRI services projected by Raleigh Radiology itself and recognized by the Agency in adding the need for an MRI in Wake County to the 2016 SMFP. In addition, the project is a very costly way to add minimal additional capacity.

Raleigh Radiology fails to document that the project is any more cost effective for Raleigh Radiology itself than the continued use of the leased MRI through Alliance. In fact, the incremental operating costs associated with the proposed project exceed the annual payments to Alliance.

For these reasons, Raleigh Radiology's application should be found non-conforming with Criterion 4.

Criterion 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.***

The Raleigh Radiology application fails to demonstrate the immediate and long-term financial feasibility of its proposal, and otherwise demonstrate conformity with Criterion 5.

As shown above, the Raleigh Radiology application's utilization projections are unreasonable, and therefore Raleigh Radiology fails to demonstrate the financial feasibility of the project. The Raleigh Radiology application contains an unreasonable assumption of growth in utilization assuming that Raleigh Radiology will continue to be able to increase capacity by adding 8 hours of operation on Sundays. It is unlikely that Raleigh Radiology can actually achieve the utilization levels it projects given the fact that Raleigh Radiology capacity projections are unreasonable and unsupported. Given that Raleigh Radiology is simply replacing a lease MRI unit from Alliance with an owned MRI unit with higher actual operating costs, the project would not be cost effective with the lower volumes that could reasonably be achieved under a reasonable capacity.

In addition, Raleigh Radiology's technologist salaries are questionable given the highly competitive nature of the Wake County market and the late evening and weekend hours that Raleigh Radiology is proposing to operate.

Furthermore, the funding letter found in Exhibit 32 to the Raleigh Radiology application does not appear reliable, and therefore the Raleigh Radiology application did not adequately demonstrate the availability of funds for the project as required under Criterion 5. The "$3,500,000" number in the Wells Fargo letter has been altered. It looks as though a piece of tape has been placed on that space because there is a background shade. One has to question what number lies underneath the piece of tape with the "$3,500,000" and who placed the piece of tape on the letter. It certainly appears that someone has cut and pasted another number ($3,500,000) over the number that was meant to be the funding number and which is typed underneath the taped over portion. In addition, the Wells Fargo letter states that an "amortization schedule" is attached to the letter, but the Raleigh Radiology application omitted the "amortization schedule." Finally, the Wells Fargo letter is not signed by the intended signee, Barbara A. Miller, but instead another individual (Michael Heil) signed on her behalf. There is nothing in the Raleigh Radiology application to indicate that Mr. Heil had the authority to sign on behalf of Ms. Miller.

For all these reasons, the Raleigh Radiology application should be found non-conforming with Criterion 5.

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

The Raleigh Radiology application fails to demonstrate that that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. Raleigh Radiology's proposed project essentially constitutes a replacement of existing equipment leased by Raleigh Radiology from Alliance and not a new unit to meet the needs of Wake County. The proposed project essentially duplicates the existing service. Further, the cost of the proposed project both in terms of capital cost and operating costs do not justify such duplication.

In addition, because Raleigh Radiology's proposed utilization projections are unreliable and not supported as discussed above, the proposed project fails to demonstrate that it will not result in unnecessary duplication as required under Criterion 6.

For all these reasons, Raleigh Radiology's application should be found non-conforming with Criterion 6.

Criterion 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.***

Raleigh Radiology fails to show evidence in its application of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

For instance, Raleigh Radiology has not documented sufficient staff to support the hours of operation of the proposed project. On page 50 of its application, Raleigh Radiology describes that the MRI will be open and scheduled Monday through Saturday for 14 hours per day and Sunday for 8 hours per day for a total of 4,678 MRI operating hours. Raleigh Radiology does not explain how it will employ staff to work late or early shifts and whether they will pay shift differential for late evenings or weekends. Technologists' salaries appear to be low based on market conditions in the highly competitive Wake County area.

For all these reasons, Raleigh Radiology's application should be found non-conforming with Criterion 7.

Criterion 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;

Raleigh Radiology's historical payor mix represents a minimal level of access to medical underserved populations. Raleigh Radiology's total provision of care to self pay/ indigent / charity and Medicaid to MRI patients for calendar year 2015 was just 2% total. This level of

access is unreasonably low. Even Raleigh Radiology's historical provision of care to Medicare patients is low at 23%. Given that MRI use rates for the senior population (65 years of age and older) is much higher than younger populations, this low level of Medicare provision is insufficient to demonstrate access to underserved populations.

Accordingly, the Raleigh Radiology application should be found non-conforming with Criterion 13(a).

. . .

c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services;

The Raleigh Radiology application does not adequately demonstrate that the medically underserved will be served by its proposed service; therefore, the application is non-conforming to Criterion 13(c). Raleigh Radiology projects an unreasonable payor mix given its historical operating experience. Raleigh Radiology has an established payor mix for the exact same service in the same location, yet it proposes a significant change in its payor mix following the opening of what constitutes a replacement MRI. While Raleigh Radiology provides some general description of its projected payor mix, none of these explanations justify the radical change in payor mix associated with this project. Most unrealistic is the increase of self pay/indigent/charity care from the historical level of 1.0% to a projected 5.8%. This is unrealistic given that the Affordable Care Act (ACA) has resulted in fewer uninsured patients. Raleigh Radiology's radical changes in projected payor mix appear to be contrived to attempt to demonstrate a greater level of accessibility to medically underserved groups. Even with the projected Medicaid increase from 1.0% to 2.0% this level of provision of care to underserved population is unreasonably low.

	2016	**2018**
Self/Indigent/Charity	1.0%	5.8%
Medicare	23.0%	30.5%
Medicaid	1.0%	2.0%
Commercial	3.0%	3.0%
Managed Care	66.0%	50.6%
Other	8.0%	8.0%
Total	100.0%	100.0%
Total Medicaid and Charity Care	2.7%	7.8%
Total Medicare, Medicaid and Charity Care	25.0%	38.4%

Source: application page 120-121

For all these reasons, the Raleigh Radiology application should be found non-conforming with Criterion 13(c).

Criterion 18a: ***The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.***

Raleigh Radiology's project will not have a positive impact on cost effectiveness given the high cost of acquiring a 3T MRI, which will essentially serve as a replacement of an existing MRI units without any meaningful increase in capacity available. It is not a cost effective use of almost $3 million in capital costs to replace an existing MRI unit with minimal increases in capacity, which does not even meet the incremental growth in demand identified by either Raleigh Radiology or the Agency in determining to add an MRI need in Wake County to the 2016 SMFP.

Raleigh Radiology will not increase access to service either. The proposed MRI will be located in the same location as an existing MRI and in the same community, Cary, where there are already multiple fixed MRI units. Geographic access will not be enhanced by this project. Raleigh Radiology will also not increase financial access given its minimal provision of Medicaid services and unrealistic self pay projections.

For these reasons, Raleigh Radiology's application should be found non-conforming to Criterion 18(a).

Comparative Analysis

The following discussion compares a variety of factors between the three applicants seeking approval to meet the need for a new fixed MRI unit in the 2016 SMFP. These three providers include:

Wake Radiology – Project I.D. # J-011172-16
Raleigh Radiology – Project I.D. # J-011159-16
DUHS – Project I.D. # J-011167-16

Need for the Project

In response to the need for a new MRI unit in Wake County identified in the 2016 SMFP, the three applicants present very different approaches to meeting the need and propose to serve different parts of the County.

- Raleigh Radiology proposes to replace its existing MRI Unit in Cary. The new scanner would not provide a meaningful increase in MRI services in Cary, where Raleigh Radiology and Wake Radiology already operate MRIs. In addition, Raleigh Radiology's project will not increase geographic access in the county and will not meaningfully add capacity to Wake County to meet growing demands for MRI services.

- DUHS proposes a new freestanding MRI unit in Holly Springs. While adding a fixed MRI scanner in Holly Springs will add a fixed MRI to a town that currently does not have a fixed MRI scanner, DUHS' project is by far the most costly among the three applicants and will provide limited access both in terms of hours of operation and its referral sources.

- Wake Radiology proposes to bring a new fixed MRI unit to Wake Forest, a rapidly growing part of Wake County, and proposes to meet the needs of neighboring Franklin County, which has lost a fixed MRI scanner with the closure of the local hospital. Wake Radiology's proposal is the most cost effective among the applicant and expands access geographically to northern Wake County while freeing up mobile capacity to meet needs in other parts of Wake County.

Wake Radiology best meets the needs identified in the 2016 SMFP and the needs of Wake County residents.

Physician & Community Support

Another 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 in a particular service area, such as DUHS.

Wake Radiology Letters of Support

Notably, Wake Radiology's application evidenced significantly more reliable project support than did that of either DUHS or Raleigh Radiology. Wake Radiology's letter represent a wide range of practices that currently refer to Wake Radiology's services and to the Wake Forest location specifically. Projected referrals contained in the letters reasonable reflect growth from historical referral patterns. Wake Radiology's letters also represent geographic diversity

including letters from Franklin County support Wake Radiology's plans to improve access to this area with limited MRI providers. Wake Radiology's letters best support its proposed project.

DUHS Letters of Support

DUHS' application contains letters of support only from providers currently affiliated with DUHS. None of the letters of support are from any non-DUHS affiliated providers. Only one letter – that from Josh Bloom, MD, MPH, CAQSM of Carolina Family Practice & Sports Medicine – references a Holly Springs office location. It is unclear if Dr. Bloom maintains any office hours in the Holly Springs office of Carolina Family Practice & Sports Medicine. Interestingly, another Carolina Family Practice & Sports Medicine practitioner, Kristen Clarey, MD, provided a letter of support for the Raleigh Radiology application. Furthermore, none of the DUHS letters of support specify any specific number of anticipated referrals of patients for MRI services. The DUHS letters of support generally state: "If DUHS is awarded the Certificate of Need, I intend to refer patients to the proposed fixed MRI scanner, as appropriate based on geographic proximity and patient preference and need. Additionally, I will continue to refer patients to Duke Raleigh Hospital's existing MRI services in Wake County, as appropriate based on geographic proximity and patient preference and need." Some of the letters of support do not reference an intent to refer at all, and merely state that the signing physician "will be able to interpret studies from this facility for any appropriate patients receiving services at this location." Accordingly, DUHS has no basis upon which to assume that it will perform anywhere near the projected number of MRI scans. It certainly as no basis to project a capture of new market share in the Holly Springs area.

Further reflecting the unreliability of DUHS' projections to capture MRI market share in the Apex or Holly Springs area, the DUHS application does not document any support from the Holly Springs community. For instance, the DUHS application does not contain any support letters from Apex or Holly Springs community officials.

Raleigh Radiology Letters of Support

Raleigh Radiology's application contains letters of support that are primarily centered around providers from Cary and Raleigh, where there is an abundant supply of fixed MRI scanners already operational. Furthermore, some of Raleigh Radiology's letters of support reflect referral patterns that are highly suspect, and thus should be disregarded. For instance, one of the letters from Melissa Korzi, a Physician's Assistant at Crescent Family Practice, provides that she referred 12 patients to Raleigh Radiology Cary for MRI services in the 12 months ending November 2015. However, the letter next states that Ms. Korzi expects "to refer hundreds of patients for MRI to Raleigh Radiology Cary each year." Crescent Family Practice is a small family medicine practice and one of its physicians, Joseph W. Bruckert, MD, did not even

provide a letter of support for Raleigh Radiology's project. In addition, Crescent Family Practice's other physician, Corey Musselman, MD, historically referred 27 patients to Raleigh Radiology's Cary MRI, and projected to refer 35 patients on an annual basis. It is simply unreasonable to think that a Physician's Assistant at a small family medicine practice would refer hundreds of patients to one MRI scanner each year. It is unreasonable to support utilization projections based on such overuse of MRI services.

Another example of an unreliable support letter for Raleigh Radiology's project is that of the letter from David Adams, MD. The support letter of Dr. Adams states that he referred 12 patients to Raleigh Radiology Cary for MRI services in the 12 months ending November 2015. It goes on to state that he expects to "refer approximately 100+ patients for MRI to Raleigh Radiology Cary each year." Dr. Adams is the only physician in a medical practice named "Office of Dr. David Adams." Based upon a review of his support letter and his website, there is nothing to justify why he would be changing his referral pattern from 12 patients annually to 100 plus. Again, it is unreasonable to support utilization projections based on such overuse of MRI services.

Raleigh Radiology's support letters speak only to Wake County, not the other counties in its proposed service area, which consist of Chatham, Durham, Harnett, Johnston and Lee Counties. The support letters mention no physicians practicing in any county other than Wake County. The support letters also reference Raleigh Radiology as providing MRI services in Wake County for many years, but fail to mention that Raleigh Radiology has provided MRI services in any other county. The support letter are yet another example of Raleigh Radiology's intent to perform MRI services in the same manner as it has historically on the Alliance MRI scanner and runs counter to Raleigh Radiology needing a 3T scanner to meet such need.

Most of Raleigh Radiology's support letters are not on the letterhead of the providers signing the letters. Some of the letters are from Physician Assistants who represent in their respective letter that the Physician Assistant is "a physician practicing in Wake County." Many of the letters will indicate the historical volume referred to Raleigh Radiology by a specific provider, but leave blank the number of future referrals, which calls into question whether the specific provider intends to refer to Raleigh Radiology for MRI services in the future. Raleigh Radiology's application states that it assumes projected referrals will be the same as historical referrals for the 12 months ending November 2015 when a provider either did not provide a letter of support or when the provider filled in the blanks for historical utilization only and not future referrals; however, there is no stated basis in the application for that assumption. The majority of the projected referrals for top referring physicians relied upon by Raleigh Radiology in Exhibit 26 of its application either did not provide a support letter or did not indicate any specific number of future referrals. Raleigh Radiology made an unsupported assumption that the referrals of these physicians for one 12 month period would be the same in the future.

Specifically, approximately 1,520 of Raleigh Radiology's projected patient referrals found in Exhibit 26 to its application were from physicians who did not even provide a letter of support; instead, Raleigh Radiology assumed future referrals would be the same as those in the 12 months ending November 2015, with no stated basis for that assumption. Another approximately 1,719 of Raleigh Radiology's projected referrals found in Exhibit 26 to its application were from physicians who did not indicate any number of future referrals; instead, Raleigh Radiology assumed future referrals would be the same as those in the 12 months ending November 2015, with no stated basis for that assumption. Of the total approximate 4,558 patient referrals relied upon by Raleigh Radiology in Exhibit 26 to its application, 3,239 (or 71%) were assumed by Raleigh Radiology with no stated basis.

Conclusion Regarding Letters of Support

In contrast to the unreliable letters of support by Raleigh Radiology and the lack of support from the Apex/Holly Springs area in the DUHS application, Wake Radiology's application contains sufficient support from physicians and community leaders. For instance, in addition to ample physician support, Wake Radiology's application also contains support letters from Franklin County and the Town of Louisburg.

In summary, lack of support from local physicians and community leaders in the Apex/Holly Springs area raises a significant question about the likelihood of MRI referrals to satisfy the volume projections in the DUHS application. This in turn casts doubt about the need for the DUHS proposal, and thus about the financial viability of the project. The unrealistic projections in some of the Raleigh Radiology support letters coupled with Raleigh Radiology relying upon referrals from physicians that either did not submit a support letter or failed to specify a number of future referrals raises a significant question about the likelihood of MRI referrals to satisfy the aggressive volume projections in the Raleigh Radiology application. This in turn casts doubt about the need for the Raleigh Radiology proposal, which is located in an area saturated with fixed MRI scanners, and thus about the financial viability of the project. By comparison, Wake Radiology's proposal is well supported by the community and local physicians, as evidenced by the letters from physicians and community leaders.

Geographic Access

Wake Radiology Geographic Access

One of the most important considerations in comparing the relative benefit of the alternative applications is the improvement of 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 Wake Forest. As demonstrated in Wake Radiology's application, Wake Forest is the fastest growing section of Wake County and this area does not currently have access to a fixed MRI scanner.

Wake Radiology will also significantly improve geographic access to residents of Franklin County. As stated in Wake Radiology's application, the lone provider of fixed MRI services in Franklin County closed towards the end of 2015 (Novant Health Franklin Medical Center). Wake Radiology's proposed site will be the most proximate provider of fixed MRI services to Franklin County. Wake Radiology's Wake Forest Office is only 7.9 mile-drive from the Franklin County line. Additionally, as discussed in Section III of its application, Wake Radiology has experienced a significant increase in the number of Franklin County patients since the closing of the county's lone fixed MRI provider. Specifically, Wake Radiology has experienced a 46.3% increase in utilization of its mobile MRI unit at the Wake Forest Office by Franklin County residents in the last six months following the closure of Novant Health Franklin Medical Center.

Wake Radiology is dedicated to serving the patients of Franklin County. On page 70 of Wake Radiology's application it commits to provide $100,000 in free MRI services to Franklin County residents in financial need. As such, Wake Radiology proposes to ensure that MRI services are both geographically and financially accessible for all Franklin County patients. No other applicant provided such an assurance

DUHS Geographic Access

Wake Radiology's proposed site in Wake Forest will offer greater geographic access to fixed MRI services than DUHS' proposed site in Holly Springs. The primary service areas (PSA) proposed by Wake Radiology and DUHS are similar in several ways. Both areas have a significant base of population and are projected to grow at a faster rate than Wake County as a whole, although, as indicated below, Wake Radiology's PSA is growing faster. Additionally, both PSAs lack a provider of fixed MRI services. In contrast, Raleigh Radiology's proposed location and its PSA have multiple fixed MRI scanners nearby. As compared to the applicants, the PSA proposed by Wake Radiology is superior in several ways.

The overall population in Wake Radiology's PSA is growing at a slightly faster rate that of DUHS. The population of those 65 and older is projected to grow at a significantly faster rate in Wake Radiology's PSA than that of DUHS. The faster growth rate is true on a percentage basis as well as in the absolute number of residents. The tables below show the growth in residents 65 and older in the two service areas proposed to be served by Wake Radiology and DUHS. The exhibits show that the population of those 65 and older in Wake Radiology's PSA will grow by 36.01 percent between 2016 and 2021 while DUHS' will grow by 28.95 percent. Additionally,

an even more importantly, Wake Radiology's PSA will grow faster in the number of residents 65 and older. The exhibits below show that Wake Radiology's PSA will grow by 5,440 while DUHS' PSA will grow by 4,819. The growth in this age cohort is important because that the age group of 65 and older utilizes MRI services at a higher rate than other age groups.

Wake Forest Area Population Growth 65 and Older

ZIP Code	2016 Population	2021 Population	Growth	Increase in Patients
27571	551	724	31.40%	173
27587	6,723	8,969	33.41%	2,246
27614	4,329	5,837	34.83%	1,508
27616	3,503	5,016	43.19%	1,513
Service Area	15,106	20,546	36.01%	5,440

Source: Claritas Marketplace

DUHS Service Area Population Growth 65 and Older

ZIP Code	2016 Population	2021 Population	Growth	Increase in Patients
27502	361	440	21.88%	79
27523	3,345	4,157	24.28%	812
27539	4,756	6,047	27.14%	1,291
27526	1,032	1,255	21.61%	223
27540	566	696	22.97%	130
27562	1,742	2,048	17.57%	306
27592	4,845	6,823	40.83%	1,978
Service Area	16,647	21,466	28.95%	4,819

Source: Claritas Marketplace

DUHS will not offer the same type of geographic access. DUHS' proposed site will not improve access for patients receiving care from non-DUHS affiliated physicians. The proposed project states several times that the fixed MRI will serve DUHS patients. Therefore, DUHS' proposed fixed MRI scanner will improve access for a relatively small number of patients in the PSA who receive care from DUHS-affiliated physicians.

Wake Radiology's project also is more geographically accessible to residents of a county outside of Wake. DUHS' proposal is significantly farther from the closest county line than that proposed by Wake Radiology. As discussed above, Wake Radiology is only 7.9 miles from the Franklin County line. In contrast, DUHS' proposed site is 18 miles away from the Chatham County line, the closest county to its proposed site.

Raleigh Radiology Geographic Access

In contrast, Raleigh Radiology proposes to locate its MRI in Cary, which will not improve geographic access because two fixed MRI scanners are located in Cary, including Raleigh Radiology's own lease MRI unit, and 3 mobile MRI scanners serve the Cary area as well as two more mobile MRI scanners just to the west of Cary. With respect to geographic access, Raleigh Radiology's project simply replaces one fixed MRI unit with another at the same location.

In its effort to create a need, Raleigh Radiology unreasonably carves Wake County into an arbitrary Northern and Southern region, and conveniently places the central area of Wake County (where all the hospitals with fixed MRIs are located) in the Northern region, even though the Cary area is geographically closer to this central area than northern areas such as Wake Forest. Raleigh Radiology then argues that the Southern region has the most need for a fixed MRI scanner, while at the same time including part of Raleigh in its proposed service area. Raleigh Radiology's application fails to adequately justify why another fixed MRI scanner should be located in Cary.

While Raleigh Radiology states its proposal is to serve an unmet need in Southern Wake County, a cursory review of Raleigh Radiology's indicates otherwise as the vast majority of Raleigh Radiology's support letters are from Raleigh and Cary providers. It is clearly apparent that Raleigh Radiology is really proposing to serve the areas of Raleigh and Cary, where fixed and mobile MRI scanners are abundant. In fact, Raleigh Radiology's proposed secondary service area presents an arbitrary attempt to carve a narrow area around the existing fixed MRI scanners located in Raleigh. (Application, p. 82) Accordingly, for all these reasons and additional ones discussed in these comments, the Raleigh Radiology proposal provides no geographic access benefit, and is the least effective alternative among the applicants.

Similarly, Raleigh Radiology's proposed service area does not rise to the level of the rapid population growth of the Wake Forest area between 2015 and 2020 which is 12.4% or the level of the 65 years old and over population growth of 36%. Rather than address the needs of the existing population, Raleigh Radiology's application focuses upon the needs of its existing patients and its desire to switch from using a mobile MRI scanner to a fixed MRI scanner. Raleigh Radiology fails to address why it cannot refer to existing providers of fixed MRI services that have capacity.

Conclusions with Respect to Geographic Access

Neither the Raleigh Radiology application nor the DUHS application propose to increase the geographic access of an entire county in the manner that Wake Radiology proposes to serve Franklin County. Wake Radiology has experienced a 46.3% increase in utilization of its mobile MRI unit at the Wake Forest Office by Franklin County residents in the last six (6) months following the closure of Novant Health Franklin Medical Center. In contrast, for instance, Raleigh Radiology includes Chatham County, Durham County, Harnett County, Johnston County and Lee County in its secondary service area. All of these counties have existing MRI

scanners (with Chatham County and Harnett County having mobile and not fixed MRI scanners). Interestingly, Raleigh Radiology's application fails to provide any support letters from referring providers in Chatham, Durham, Harnett, Johnston and Lee Counties. Instead, as noted herein, Raleigh Radiology's support for its project is primarily from providers in Cary and Raleigh, where the market is saturated with fixed and mobile MRI scanners. Adding yet another fixed MRI scanner in the Cary/Raleigh market will not improve geographic access.

In summary, based on the current locations of existing fixed MRI scanners in Wake County, the Wake Forest Area proposed to be served by Wake Radiology is underserved with respect to access to fixed MRI services. Wake Radiology proposes to serve a much more populous primary service area with no fixed MRI scanners than either DUHS or Raleigh Radiology. Furthermore, the proposed Wake Radiology fixed MRI scanner is located further from existing fixed MRI scanners than either DUHS or Raleigh Radiology proposals. Raleigh Radiology proposes to place its fixed MRI scanner in Cary with numerous fixed MRI scanners nearby. Accordingly, the proposed fixed MRI scanner at Wake Radiology's Wake Forest Office is the most effective alternative and comparatively superior among all the applicants for improving geographic access to fixed MRI services.

Capital Costs

In its application, Wake Radiology demonstrates that its proposal is the most effective and reasonable alternative in terms of cost, design, means of construction, and equipment acquisition, and that the Wake Radiology project will not unduly increase the costs of providing health services, or the costs and charges to the public of providing health services. Wake Radiology will locate its MRI in close proximity to its existing imaging center in Wake Forest. Renovating existing space and co-locating near existing services allows Wake Radiology to be the most cost effective applicant, as compared to DUHS proposing to establish a new freestanding center and Raleigh Radiology proposing to acquire an expense 3T scanner when a less costly 1.5T scanner is the better alternative. The following table compares project-related costs among the three applicants:

Project Costs

	Wake Radiology	DUHS-Holly Springs	Raleigh Radiology
Capital Cost	$1,779,992	$5,965,000	$2,922,552
% Higher than Wake Radiology	---	235%	64%

Source: CON Applications

In the current healthcare environment, 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. Wake Radiology projects by far the lowest project costs among the applicants.

Accessibility for Medically Underserved Populations

As documented in its application, if Wake Radiology is awarded a fixed MRI scanner, Wake Radiology is committed to provide $100,000 in free MRI services to financially needed patients from Franklin County. No other applicant made such a committed in their respective application. Wake Radiology takes pride in providing care to persons covered by government insurance or depending upon charity care. Wake Radiology provides charity care, and a projected MRI Medicare and Medicaid payor mix above 46.6%. As a for-profit healthcare entity with no legal obligation to provide charity care, Wake Radiology invests considerable resources in extending healthcare services to the medically underserved.

Wake Radiology is the most financially accessible of the three projects with a combined 8.2 percent of services provided to underserved populations including Self Pay/Indigent/Charity and Medicaid patients. Wake Radiology also projects to provide the highest percentage of services Medicare patients as shown below.

	Wake Radiology	**Raleigh Radiology**	**DUHS-Holly Springs**
Self/Indigent/Charity	1.9%	5.8%*	1.9%***
Medicare	38.4%	30.5%	27.4%
Medicaid	6.3%	2.0%**	5.2%
Commercial	0.2%	3.0%	1.2%
Managed Care	51.7%	50.6%	57.6%
Other	1.5%	8.0%	6.7%
Total	100.0%	100.0%	100.0%
Self/Indigent/Charity & Medicaid Subtotal	**8.2%**	**7.8%**	**7.1%**
Self/Indigent/Charity, Medicaid and Medicare Subtotal	**46.6%**	**38.3%**	**34.5%**

**Raleigh Radiology's projected self pay percentage is unrealistic given its historical provision of 1% self pay care and the impact of the ACA on the number of uninsured patients.*
***Raleigh Radiology's projected Medicaid percentage is unrealistic given its historical provision of 1% of services to Medicaid patients.*
****DUHS projections of charity care and self pay patient volume and write offs are inconsistent within its application.*

Wake Radiology is committed to providing the medically underserved with quality healthcare services. Wake Radiology also acknowledges that DRH and DUHS by nature, as not-for-profit entities, also provide extensive care to the medically underserved. Because of the distinctly different tax statuses of Wake Radiology as compared to DRH and DUHS, Wake Radiology is

not directly comparable to DRH and DUHS in terms of expanding access to the local medically underserved population. Wake Radiology should be found most effective with respect to financial accessibility.

Staffing

In terms of support for the proposed MRI units, Wake Radiology provides the most complete staffing for the proposed project. Wake Radiology proposes 5 FTE MRI Techs (including supervisor) for 78 hours of operation per week compared to Raleigh Radiology's projection of 5.07 (including supervisor) MRI Techs and Tech Assistance for 92 hours per week. Wake Radiology proposes 4 FTEs for MRI Technologists compared to DUHS' projection of 1.62 FTEs for MRI Technologists. DUHS also project to have 1.62 FTEs for a Clinical Nurse II, but does not document how the Clinical Nurse II supports the MRI unit. Clinical nurses are not trained for MRI technology roles. Wake Radiology staff will provide greater coverage during operations and a higher level of training as Wake Radiology does not proposed to use Technology Assistants.

Projected Year 2 Staffing

	Wake Radiology	Raleigh Radiology	DUHS-Holly Springs
Clinical Staff			
MRI Supervisor	1.0	1.09	0.25
MRI Tech	4.0	2.60	1.62
Tech Assistants	0	1.42	0
Nurse	0	0	1.62
Total	5.0	5.07	3.49

In addition, both Raleigh Radiology and DUHS appear to project comparatively low salary levels for technologists in the competitive Wake County market s shown below. Wake Radiology projected salaries are based on its experience in providing MRI in multiple freestanding locations similar to those proposed by the three applicants.

	Wake Radiology	Raleigh Radiology	DUHS-Holly Springs
Radiology Tech Salary	$ 81,482	$73,847	$76,879

Timing

DUHS' proposed MRI scanner will be located in a medical office building that has not been constructed. This will cause a significant delay in provision of care. On page 159 of its application, DUHS states that it will begin operating the MRI scanner on July 1, 2018. In

comparison, both Wake Radiology and Radiology propose to begin operating their respective MRI scanners in May 2017, more than one full year prior to DUHS. Therefore, Wake Radiology and Raleigh Radiology will more quickly meet the needs of Wake County patients.

Proposed Scheduling

DUHS does not plan to offer MRI services for at least 66 hours per week until year three of operation. While this is no longer a requirement under the MRI Criteria and Standards, DUHS short operating hours limit its accessibility and confirm less and sufficient demand for its services. It proposes to operate just 45 hours per week in year one and 55 hours per week in year two. Additionally, DUHS does not propose to offer the service on weekends. DUHS claims that the proposed project will greatly improve patient convenience by allowing for more scans to be performed by its system during weekday hours, but ignores patients that are only available to receive care on weekends.

Raleigh Radiology already operates 84 hours per week for its existing leased MRI scanner in Cary. While Raleigh claims it will increase its hours of operation to 92 by adding Sunday time slots the ability to increase capacity by continuing to expand hours reaches diminishing returns. A relatively small number of patients will choose to have their MRI scan performed at 9 pm on weeknights or Saturday and Sunday. Ultimately, Raleigh Radiology's extended schedule, however, does little to increase capacity to meet the growing demand for MRI services in Wake County because its proposal is simply a replacement of existing MRI capacity.

In comparison, Wake Radiology proposes to offer its MRI services 78 hours per a week in year one and offer weekend availability. This schedule is more accessible than DUHS and adds more capacity to Wake County than Raleigh Radiology's replacement project. Therefore, Wake Radiology better meets the identified need for an additional fixed MRI scanner in Wake County.

* * * *

Raleigh Radiology's application does not meet the need in the 2016 SMFP and does not provide sufficient capacity to meet the need for growth in demand for MRI services in Wake County. Raleigh Radiology's project is not a cost effective use of almost $3 million of resources as it duplicates the existing MRI already operated by Raleigh Radiology in the same location. Raleigh Radiology's project is not cost effective operationally either given that operation of the proposed unit is more costly than the existing Alliance lease. Raleigh Radiology's project is comparatively inferior to Wake Radiology in terms of enhancing geographic access and financial access. Raleigh Radiology's application should be denied and Wake Radiology's application should be approved.

Attachment A

Comparison of 3T and 1.5T MRI Units

APPENDIX 1: PROS AND CONS OF 1.5 T MRI VERSUS 3.0 T MRI

Table 10: Budgetary Cost Comparison, 1.5 T MRI to 3.0 T MRI (for example, only)*

	1.5 T MRI	1.5 T MRI	1.5 T MRI	Magnitude of Difference (1.5 T MRI to 1.5 T MRI)		3.0 T MRI	3.0 T MRI	3.0 T MRI	Magnitude of Difference (3.0 T MRI to 3.0 T MRI)		Magnitude of Difference (1.5 T MRI to 3.0 T MRI)	Magnitude of Difference (1.5 T MRI to 3.0 T MRI)
Capital (MRI only)	**Basic**	**Mid**	**Premium**	**Basic vs. Prem.**		**Basic**	**Mid**	**Premium**	**Basic vs. Prem.**		**Basic vs. Basic**	**Premium vs. Premium**
MRI system cost	**32 Channel**	**48 Channel**	**64 Channel**			**48 Channel**		**64 Channel**				
(Active shielding)	$1,788,200	$1,788,200	$1,788,200			$2,642,200		$2,642,200				
Alternative gradients and receiver channels		$99,455	$198,910					$99,455				
*Clinical Options**			$658,300					$658,300				
Angio DOT**		$33,155	$33,155					$33,155				
Tim Table/Angio DOT **		$62,160	$62,160					$62,160				
Cardiac DOT**		$62,160	$62,160					$62,160				
Knee DOT**		$16,575	$16,575					$16,575				
Total	**$1,788,200**	**$2,061,705**	**$2,819,460**	**$1,031,260**		**$2,642,200**		**$3,574,005**	**$931,805**		**$854,000**	**$754,545**
Other hardware & software available	Yes	Yes	Yes	Yes		Yes		Yes				
Reference	Siemens Canada Limited, unpublished data, 2010											

MRI = magnetic resonance imaging; T = Tesla; vs. = versus.

* Clinical options example (will vary depending on programs supported by the imaging service and site preference)
** DOT (Day Optimization Throughput): Technologist scanning assistance program

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Safety Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Immediate fringe field surrounding magnet	--	A ferromagnetic object inadvertently brought into the scan room will experience a sharp increase in attraction toward the 3.0 T MRI magnet upon approach to the scanner (versus a 1.5 T MRI).[34]
Implanted devices	--	Not all objects tested on a 1.5 T MRI have been tested on a 3.0 T MRI; therefore, if a 3.0 T is the only scanner on site, patients with certain implanted devices cannot be scanned.[34]
Consequence of failed actively shielded magnet	--	If active magnetic shielding malfunctions, the unshielded primary magnet field will bloom to several times its normal size and the extended fringe field may interfere with nearby CT, PET, and other imaging equipment not affected by a 1.5 T MRI. Patient monitoring equipment, drug delivery systems, and life support systems may be affected.[34]
Gradient noise	--	Higher gradient performance at 3.0 T MRI results in higher sound pressure levels (although manufacturers have improved techniques to dampen the noise).[34]
Pulsed radiofrequency (RF) fields/ Specific Absorption Rate (SAR)	--	Heating potential is notably higher and more significant at 3.0 T. Higher RF power levels result in limitations on SAR that may not allow the shortest possible scan times using 180 degree RF pulses. Many manufacturers have incorporated reduced tip angle pulse techniques to mitigate this problem.[39]
Imaging coils and cable leads	--	If the coil array, cable assembly, or connector malfunctions and is in physical contact with the patient, skin irritation or burning may occur. The use of a higher magnetic field and higher radiofrequency power levels make such a failure at 3.0 T more critical.[34,39]
Technical Issues	**3.0 T MRI Pro**	**3.0 T MRI Con**
Signal to Noise Ratio (SNR)	SNR received at 3.0 T MRI is approximately twice that of SNR received on a 1.5 T system, hence the abundance of SNR can be used to improve image quality or decrease scan time.[40,41]	--
Parallel Imaging (PI)	PI techniques reduce scan time but are accompanied by loss of signal; however, the resulting image quality can be comparable to a 1.5 T due to the abundance of signal at 3.0 T.[40-42]	--
Relaxation rates	Increased T1 relaxation time for solid tissue and the relatively constant T1 for blood results in an overall improvement in blood vs. background tissue contrast when MR angiography pulse sequences are used.[41,42]	Conventional spin echo pulse sequences cannot be used to produce ideal T1 contrast weighted scans since T1 relaxation time increases with the magnetic field strength. Alternative pulse sequences such as T1 weighted gradient echo, spoiled gradient echo, or magnetization-prepared rapid gradient echo can be used instead.[40]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Technical Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Spatial resolution	Increased SNR leads to an ability to increase in-plane resolution or decrease slice thickness; i.e., higher spatial resolution results in improved image clarity and diagnostic strength.[40]	--
Temporal resolution	Improved temporal resolution occurs with shorter scan times.[40]	--
Artifacts from breathing and motion	Decreased scan times help reduce data artifacts related to breathing and patient motion in those with difficulty holding still during the scanning process.[43]	Artifacts resulting from breathing or any type of motion including flowing blood or pulsation of cerebrospinal fluid are more prominent on 3.0 T MRI vs. 1.5 T MRI. To various extents, manufacturers offer motion-compensating features to reduce or mitigate the problem.[44]
Spectroscopic imaging	Improved spectral resolution or the ability to visualize changes in peaks in metabolites. Fat-water suppression techniques are also improved; especially beneficial for musculoskeletal studies in which fat suppression imaging are important.[41,45]	--
Functional MRI using the BOLD technique	At 3.0 T MRI, clinical BOLD functional imaging studies are excellent, practical, and robust. Greater susceptibility contrast sensitivity and higher SNR inherent to 3.0 T scanning can produce up to a 40% increase in detected activation.[41,42]	--
Diffusion Weighted Imaging (DWI)	Increased sensitivity for detection of ischemic lesions in acute stroke.[41,45]	Increased susceptibility may lead to image distortion during echo planar MRI, which is typically used for DWI. Planar imaging techniques may significantly reduce DWI susceptibility artifacts.[41]
Diffusion Tensor Imaging (DTI)	Images of white matter tracts are improved at 3.0 T MRI compared with 1.5 T MRI; 3.0 T enables DTI at higher spatial resolution or shorter acquisition times.[42]	Geometric warping artifacts common to EPI pulse sequences may limit anatomic fidelity, especially in area of high magnetic field susceptibility resulting from high interfaces such as brain-to-air-to-bone in the area of the skull base and the posterior fossa.[42]
Perfusion-Weighted Imaging	The accuracy of cerebral perfusion is improved at 3.0 T MRI because of the increased number of sampling points during the first pass of gadolinium contrast agent compared with DWI imaging at 1.5 T MRI with much lower temporal resolution and a smaller number of sampling points.[41,45]	--
Magnetic resonance angiography (MRA)	Improved Contrast to Noise Ratio (CNR). The longer T1 of background tissues can be exploited for superior inflow MRA. Vessels show more hyper-intense signals with better background tissue suppression. Small vessel visualization is improved.[42]	--

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Technical Issue	**3.0 T MRI Pro**	**3.0 T MRI Con**
Arterial Spin Labelling (ASL)	Signal captured from blood is used to image vessels with the ASL pulse sequence. ASL at 3.0 T MRI have higher SNR and longer T1 relaxation, resulting in more reliable ASL.[41]	--
Magnetic susceptibility	Increased magnetic susceptibility can have a positive effect due to 3.0 T being more sensitive to the deposition of blood products (that is, hemosiderin). Improved imaging for brain hemorrhage can be seen in head trauma or stroke. 3.0 T can be useful for dynamic susceptibility weighted perfusion MRI to determine functional parameters such as cerebral blood flow.[41,46]	There can be a signal void in areas of air-to-tissue interfaces such as the frontal sinus, skull base, orbits, and frontal lobes of the brain. Hyper- and hypo-intense signal artifacts due to the presence of implanted metal hardware may be reduced by use of wider receiver bandwidth and longer echo train lengths. Susceptibility leads to dephasing, geometric distortion and signal loss, typically in gradient echo pulse sequences.[41,46]
Chemical shift	MR spectroscopy benefits from an increased chemical shift and improved spectral resolution.[41,46]	Chemical shift artifacts are a disadvantage for imaging cartilage and bone interfaces of musculoskeletal areas.[46]
Dielectric artifacts	--	Radiofrequency waves transmitted from the transmitter coil into the patient are reduced in speed and wavelength in various tissues. As a result, there can be strong variations in signal intensities across the images, brightening in regions away from the receiver coil, or dark areas caused by constructive or destructive interference from standing waves. The dielectric artifacts are more prominent on 3.0 T MRI vs. 1.5 T MRI systems and presents as a challenge when imaging the heart. New 3.0 T scanners use multi-transmit radiofrequency or appropriate modulation in amplitude and phase of the radiofrequency pulse to reduce the problem. Phased array coils and PI may also help.[40,42,46]
Gadolinium	A standard dose of gadolinium administered for examinations done on a 1.5 T MRI may result in greater sensitivity in 3.0 T MRI (that is, less contrast may be used or the same dose may improve CNR).[41,42]	-
Imaging coils	--	The variety of coils for 3.0 T MRI scanners may be limited, depending on the generation of the scanner, especially for systems where the ADC converter is integrated into the imaging coil.[40,43]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Clinical Condition	**3.0 T MRI Pro**	**3.0 T MRI Con**
Brain: Multiple sclerosis	Lesion visualization is improved.[41,47]	--
Brain: DWI for stroke	Increased sensitivity for detection of ischemic lesions, especially in patients with multiple cerebral embolisms.[41,47,48]	Image distortion in echo-planar DWI due to susceptibility; can be reduced by use of PI.[41,47,48]
Brain: DTI	Imaging of white matter tracts is improved at 3.0 T MRI versus 1.5 T MRI.[42,45]	Geometric warping artifacts common to EPI pulse sequences may limit anatomic fidelity, especially in areas of high magnetic field susceptibility resulting from high interfaces such as brain-to-air-to-bone at the skull base and the posterior fossa.[42]
Brain: Spectroscopy (MRS)	Improved spectral resolution for evaluation of metabolites that could be obscured at 1.5 T MRI. Ability to perform multinuclear spectroscopy to analyze many neurological disorders. The gain in SNR and improved line separation at 3.0 T enable use of smaller voxels, which results in an improved quantification of metabolites, especially for the adjacent creatine and choline peaks.[41,45,49]	--
Brain: Dynamic Susceptibility-Weighted Perfusion MRI (DSW-PMR)	Improved because of the increase in magnetic susceptibility effects. Improved diagnostic information to help determine brain tissue viability after stroke or TIA. The accuracy of cerebral perfusion is improved at 3.0 T MRI owing to the increased number of sampling points during first pass of gadolinium contrast agent compared with DSW-PMR imaging at 1.5 T MRI with lower temporal resolution (e.g., 1.5 seconds per dynamic acquisition) and a smaller number of sampling points.[41,45]	--
Brain: Functional MRI	Increased CNR using BOLD technique. Improved sensitivity and specificity.[41,48]	--
Spine	Improved image quality with 3.0 T MRI DTI vs. 1.5 T MRI.[48]	Decreased fluid contrast associated with prolonged T1. Can be resolved by use of T1 fluid-attenuated inversion recovery (FLAIR), which delineates soft tissue, CSF, disc, and bone interfaces well.[42]
Liver	Effects of fat saturation are improved at 3.0 T MRI because of stronger chemical shift between fat and water.[43]	3.0 T MRI is more sensitive to respiratory motion, vascular pulsation, and dielectric effect. Tissue heating is also a concern. Dual phase imaging can be problematic because the phase echoes are too close together. Adrenal gland imaging may be challenging. Chemical shift artifacts are more pronounced at fat-to-water interfaces.[48]

Table 11: Pros and Cons of 1.5 T MRI vs. 3.0 T MRI; Safety and Technical Issues, and Clinical Applications		
Clinical Condition	**3.0 T MRI Pro**	**3.0 T MRI Con**
Pelvis	Structures of the prostate gland may be demonstrated adequately without insertion of an endorectal coil.[48]	Optimal high resolution imaging of the prostate best done with an endorectal coil and pelvic coil combination.
Breast	Improved spatial and temporal resolution capabilities; improved detection and characterization of breast cancer with 3.0 T MRI.	--
Musculoskeletal system	Higher SNR, smaller field of view, thinner slices, and increased spatial resolution can be obtained. Enhanced detection of articular cartilage tears of the shoulder and hip labrum, triangular fibrocartilage complex tears of the wrist, and diagnosis and staging of various derangements of the knee and elbow.[42,48]	T1 increased by 10% to 30% when imaging at 3.0 T MRI vs. 1.5 T MRI. Repetition time must be increased to maintain T1 weighted contrast. The increase in TR is typically about 20%, which translates into a longer TR time. Spectral fat suppression is sensitive to magnetic field inhomogeneity, which limits its use in tissues displaying susceptibility artifacts and in the postoperative areas with hardware due to enhanced artifacts from metal.[42,50]
Cardiac	Ability to obtain higher spatial and temporal resolution. (Increased SNR and decreased imaging time compared with a 1.5 T MRI.) Perfusion images provide better visual delineation of perfusion abnormalities and cardiac ischemia evaluation.[48,51,52]	Cine sequences using steady state free precession pulse sequences for cardiac imaging to display wall motion and LVEF at 3.0 T MRI can be problematic due to increased artifacts from radiofrequency inhomogeneity (dark banding or flow artifacts). MR systems equipped with multi-transmit radiofrequency PI or techniques to modulate the amplitude and phase of radiofrequency pulses can reduce the dark banding artifacts.[48,50-52]
Pediatric imaging	Improved image quality due to higher SNR is available to demonstrate the small anatomical structures of a pediatric patient, and shorter scan times result in reduced total visit time.	--
Vascular	3.0 T MRI TOF imaging due to the longer T1 of background tissue; results in background tissue suppression and higher visibility of contrast in the vascular structures. Use of PI for non-contrast and contrast-enhanced techniques allow for shorter scan times, with increased resolution. Improved temporal resolution vs. 1.5 T MRI.[41,48]	--

ASL = arterial spin labelling; BOLD = blood oxygen level-dependent; CNR = contrast-to-noise ratio; CSF = cerebrospinal fluid; CT = computed tomography; DTI = diffusion tensor imaging; DWI = diffusion-weighted imaging; EPI = echo planar imaging; FLAIR = fluid attenuation inversion recovery; LVEF = left ventricular ejection fraction; MRA = MR angiography; MRI = magnetic resonance imaging; MRS = MR spectroscopy; PET = positron emission tomography; PI = parallel image; PMR = perfusion MR; SAR = Specific Absorption Rate; SNR = signal-to-noise ratio; T = Tesla; TIA = transient ischemic attack; TOF = time-of-flight; vs. = versus.