

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 Comments by Wake Radiology Services, LLC and Wake Radiology Diagnostic Imaging, Inc. regarding Duke University Health System, Inc.'s Certificate of Need application to acquire a fixed MRI scanner in Wake County, North Carolina (Project I.D. # J-011167-16)

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 Duke University Health System, Inc. ("DUHS") 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 – DUHS's application, Wake Radiology's application (Project I.D. # J-011172-16) and Raleigh Radiology, LLC's application (Project I.D. # J-011159-16). Wake Radiology is also filing separate comments regarding Raleigh Radiology, LLC's 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,

A handwritten signature in cursive script that reads "Kathryn MT Platt".

Kathryn MT Platt
President

**COMMENTS REGARDING DUKE UNIVERSITY HEALTH SYSTEM, INC.'S
CERTIFICATE OF NEED APPLICATION TO ACQUIRE A FIXED MRI SCANNER
Project I.D. # J-011167-16**

**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 DUHS 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 DUHS Application

The application submitted by DUHS 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. DUHS' project is not cost-effective and access to the proposed service will be limited. The financial feasibility of the project is questionable given that the financial projections are missing significant expense categories.

By contrast, the application filed by Wake Radiology to acquire a fixed 1.5T MRI scanner to be located near its 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 DUHS' application should be denied.

The following discussion identifies specific failures of DUHS' 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.

DUHS's proposed project is inconsistent with the basic principles of the SMFP under Policy GEN 3. The proposal is not cost-effective. DUHS's capital costs are very high—\$5,965,000—and DUHS has not adequately demonstrated the reasonability of these capital cost for the project. In addition, the DUHS proposal has only \$80,000 of start-up and operating expenses in working

capital, which is woefully insufficient and conflicts with the financial projections in the application.

The DUHS proposal also fails to enhance access for all Wake County residents. Throughout the application, DUHS stresses that the proposed MRI is focused upon serving the existing DUHS patient base. DUHS does not adequately demonstrate that the proposed MRI will be accessible to patients who receive care from non-DUHS affiliated physicians. For instance, page 20 of the application states that “[t]he proposed project will also improve geographic access to MRI services for DUHS patients...” Further, all of the physician letters of support in Exhibit 16 are from DUHS-affiliated physicians. In response to Application Question V.4(c) which asks the applicant provide any documented evidence of specific support for the proposal from “other groups/individuals who could affect the project’s success, e.g., healthcare providers or health-related agencies”, the DUHS application refers to the DUHS administration and responds that this project “fits into DUHS’ overall strategic plan for growth in Wake County. . . .” and fails to document any support for this project outside of DUHS or its affiliated entities. (DUHS application, p. 107) The DUHS application lacks any documented support from the local communities of Apex and Holly Springs. Accordingly, the DUHS application shows that the proposed MRI scanner will not be accessible to a majority of Wake County residents, but focused upon the internal needs of DUHS.

For all of these reasons, the DUHS 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, DUHS has not adequately demonstrated that it meets the minimum volume standards under 10A NCAC 14C.2703(3).

DUHS relies on unsupported market share increases to meet such projections. Further, DUHS’ support for the project, which is limited to physicians affiliated with the Duke University Health System, does not support the increased market share that DUHS projects to achieve. In addition, DUHS application projects the weighting factor for Duke Radiology Holly Springs based upon an unreliable partial year experience of Duke Imaging Services – Cary Parkway (DIS-CP). If the most recent full year of utilization experience for DIS-CP is used then DUHS falls short of its projected weighted MRI scans and also fails to meet the performance standards under the MRI Criteria and Standards as shown below.

DUHS Projected Weighted Scans Based on Historical Experience

	DIS-CP FY 2015 Percent	DUHS - Holly Spring	
		Projected Unweighted Scans	Projected Weighted Scans
Contrast	34.5%	1,532	1,685
No Contrast	65.5%	2,908	2,908
Total	100.0%	4,440	4,593
Performance Standard			4,805

DUHS should be found non-conforming with the MRI Criteria and Standards Performance Standards.

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.

Access Is Limited To Duke University Hospital System Patients.

The DUHS application proposal does not adequately demonstrate the need that its identified population has for the services proposed. As stated above, the DUHS application limits access to the proposed MRI to the existing DUHS patient base. Therefore, it fails to improve access for all service area residents, as required by this criteria. DUHS is seeking to acquire a fixed MRI scanner and develop Duke Radiology Holly Springs to serve its own DUHS patients. Such intent is reflected throughout the DUHS application.

For instance, all of the physician letter of support provided in Exhibit 16 to the DUHS application were written by DUHS-affiliated physicians. DUHS shows no plans to make the proposed MRI scanner available to all Wake County residents, including those having no prior affiliation with the DUHS system. DUHS's proposed project is narrowly focused on the patients of a single health system without regards to all other patients in Wake County. As will be discussed, DUHS projects significant increases in market share to achieve its projected MRI volume. These increases are inconsistent with DUHS' limited pool of referral sources from within the DUHS system.

Further evidencing this restrictive nature of DUHS' proposal, while DUHS repeatedly states in its application that there is a need for residents of Holly Springs, Apex, and southern Wake County to have convenient local access to fixed MRI services, DUHS fails to adequately document any local community support or local physician support from those areas for its project. Physicians refer patients for MRI services, so physician support for an MRI scanner is essential. This is particularly true for a proposed new provider in a particular service area, such as DUHS in the Holly Springs area. Yet, only one support letter in the DUHS application – from 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.

Overall, the DUHS application's volume projections are not supported by and are inconsistent with the support letters in the application. This flaw is amplified with regard to the DUHS application due to DUHS' failure to provide reasonable assumptions supporting its projected utilization, as discussed below. All of which render the application's volume projections unreliable.

In contrast, Wake Radiology will not limit access to its proposed fixed MRI to patients of a single health system and will be available to all Wake County residents, as well as those of

Franklin and surrounding counties. Access to Wake Radiology's MRI scanner will also be accessible to patients of all appropriate physician groups and health systems.

DUHS Did Not Adequately Demonstrate Its Project Is Accessible To Underserved Populations.

DUHS claims that it will increase access to the underserved. On page 116 of its application, DUHS states that it will provide \$157,398, 7.13 percent of gross revenue, in charity care. However, this projection is wholly inconsistent with the pro forma projections in the DUHS application. Form C shows that DUHS will have \$42,350 in self-pay gross revenue. Self-pay is generally the payor source classification for charity care patients. DUHS does not explain how it projects to provide almost four times the amount of charity care in comparison to its small self-pay projection. Further, the projected payor mix on page 124 of the DUHS application shows just 1.9% of procedures will be self-pay patients. This inconsistency and low projection of charity care shows that DUHS will not be a financially accessible provider, as proposed in the DUHS application.

DUHS's Project Will Not Be Available For An Extended Period of Time.

DUHS's 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, which casts further doubt on the need for DUHS' proposal. On page 159 of its application, DUHS states that it will begin operating the MRI on July 1, 2018. This extended two-year implementation schedule will delay bringing needed MRI capacity to Wake County.

DUHS Will Not Be Accessible Due To Limited Operating Hours.

DUHS does not plan to offer MRI services for at least 66 hours per week until year three of operation. 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. All of this casts further doubt on the need for DUHS's proposal.

DUHS Does Not Reasonably and Accurately Project the Utilization of the Proposed MRI Unit.

DUHS' projected utilization is inconsistent and not supported by reasonable assumptions based on several factors, as discussed below.

Baseline Market Share Increases

Projected MRI utilization in DUHS' primary service area (consisting of Apex and Southwest Wake County sub-regions with zip codes 27502, 27523, 27539, 27526, 27540, 27562, and 27592) and DUHS' secondary service area (consisting of the remaining Wake County area zip codes) is projected to align with population growth. (See page 59.) DUHS projects MRI demand to increase by 1 to 2 percent annually based on population growth by sub-area of Wake County and constant MRI use rates. (See page 59).

Despite this modest growth in overall demand, DUHS projects Duke Raleigh Hospital's fixed MRI scanner will experience an over 5% increase in utilization per year through 2021. (See page 63.) Duke Raleigh Hospital's mobile MRI unit will experience an over 5.7% increase in utilization per year through 2021. (See page 63.) Finally, Duke Imaging Services – Cary Parkway's (DIS-CP) MRI unit will experience an over 5.0% increase in utilization through 2021. (See page 64.) In order to achieve these projections, DUHS must achieve significant market share increases across its other MRI units because DUHS is projecting volume increases that significantly exceeds the population growth and resultant MRI growth for the area.

The DUHS application does not document the basis for projecting this capture of additional market share nor even acknowledge the market share growth needed to achieve these baseline projections. Indeed, as noted above, the DUHS application describes its need for the project as servicing the existing DUHS patient population. Without adequately documenting the assumptions for proposing to capture additional market share, the DUHS application's projected volumes are unreasonable.

Holly Springs Market Share Increases

The DUHS application identifies an estimated 1,416 MRI scans performed on DUHS patients who reside in the identified primary service area at each of its three existing Wake County locations. (See pages 61-62.) The DUHS application estimates that 1,265 of these patients will shift from existing DUHS MRI units to the proposed new Holly Springs MRI. (See page 67.) To this number, DUHS projects another incremental increase of 2,509 MRI procedures between 2016 and 2021 based on additional market share capture. (See page 68.) However, it is not clear where this incremental market share will come from given that the expected referral base will remain Duke-affiliated physicians and the DUHS application failed to document local physician and community support in its proposed primary service area.

Furthermore, DUHS' market share increases are unreasonable and double counted rendering the projected volumes unreasonable. DUHS assumes market share increases for the system's MRIs based on the projected 5% annual growth rate, which exceeds the projected area average growth rate and then an additional layer of market share growth added at the proposed new Duke Radiology Holly Springs facility. The DUHS application, however, does not adequately document the assumptions to support these projections. Without adequately documenting the assumptions upon which projected utilization is based, the DUHS application's projected volumes are unreasonable.

Unreasonable Weighted MRI Projections

The DUHS application projects the weighting factor for Duke Radiology Holly Springs based upon the experience of the Duke Imaging Services – Cary Parkway (DIS-CP). While this facility may be a reasonable surrogate for the new Holly Springs facility, DIS-CP experience for a partial year of 2016 leads to likely unreliable results. For the partial year 2016 (8 months July 2015 to February 2016), DIS-CP experienced a weighting factor of 42% scans with contrast. (See page 76.) The prior actual reported year for Duke Imaging Services – Cary Parkway (DIS-CP) provided weighting of 34.5% ($431/1,248 = 34.5\%$), well below 42%. (See page 64.) This rapid increase in contrast use in a partial non-reporting period raises questions regarding DUHS's projections. If the most recent full year of utilization experience for DIS-CP is used then DUHS

falls short of its projected weighted MRI scans and also fails to meet the performance standards under the MRI Criteria and Standards as shown below.

DUHS Projected Weighted Scans Based on Historical Experience

	DIS-CP FY 2015 Percent	DUHS - Holly Spring	
		Projected Unweighted Scans	Projected Weighted Scans
Contrast	34.5%	1,532	1,685
No Contrast	65.5%	2,908	2,908
Total	100.0%	4,440	4,593

For all of these reasons, the DUHS 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 DUHS application fails to demonstrate that the least costly or most effective alternative has been proposed, and otherwise demonstrate conformity with Criterion 4. The DUHS proposal is to install a new fixed MRI scanner in a new medical office building to be located in Holly Springs, where DUHS is not currently present. DUHS is a new provider to the Holly Springs area. DUHS' proposed capital costs are \$5,965,000, with an additional \$80,000 in working capital for start-up and initial operating expenses. Please see the Comparative Review section of these comments for more specific information about how DUHS' costs compare to the other applicants.

The proposed capital cost is very high for the addition of a single fixed MRI scanner because DUHS is proposing a new imaging center location with a single modality. This is a much more expensive alternative than adding MRI services to an existing facility with share costs among modalities. This is true for both project costs and operating costs. DUHS includes site acquisition, site preparation, and other costs associated with the construction a new medical office building. Therefore, DUHS fails to show that its proposed project is either the least costly or most effective alternative.

For all of these reasons, DUHS 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 DUHS application fails to demonstrate the immediate and long-term financial feasibility of its proposal, and otherwise demonstrate conformity with Criterion 5. Included in this nonconformity, the DUHS application fails to include certain significant expense items in its financial projections, as shown below.

Global Charges and Professional Fees Are Not Included

On page 14 of its application, DUHS states that “DUHS will develop the proposed fixed MRI as an off-campus, free-standing MRI services...” As a free-standing MRI provider, DUHS should have included the costs associated with the reading of the MRI scans. Freestanding MRI providers bill globally and global fees (technical and professional fees) should be reflected in this application.

However, DUHS fails to include any expense associated with the professional fees for reading the MRI images. The DUHS application states that the MRI images will be read by Private Diagnostic Clinic, PLLC (PDC), a DUHS-affiliated practice. The DUHS application references that there will be a professional services agreement with PDC to provide radiology services. (DUHS application, p. 131) However, DUHS fails to include any expense associated with PDC’s services. The lack of this significant expense impacts the financial feasibility of the proposal, and renders the financial projections unreliable and unreasonable.

DUHS Fails To Adequately Account For Start-Up Costs and Operating Expenses.

The DUHS application fails to adequately account for start-up and initial operating expenses. Page 142 of the application shows total estimated start-up expenses of \$30,000 and an estimated initial operating period of three months. They also listed initial operating expenses of \$50,000 and a total working capital requirement of \$80,000. However, this amount is woefully insufficient. DUHS’ financial projection show that it will lose \$40,837 in year one.

On page 142 of the application, DUHS states that it will only take three months for total revenues to equal total expenses. If break-even occurs so early, how is it possible to operate at a loss for the entire year? The estimated initial operating period should have been listed as far longer than three months and total working capital should be listed as far more than just \$80,000. Accordingly, the DUHS application’s total working capital is unreliable and unreasonable.

DUHS Staffing Expense Does Not Appear To Be Sufficient.

DUHS will need administrative, clinical and support staffing for its new freestanding imaging center. However, DUHS does not sufficiently explain how all administrative, clinical and support staff will be provided and whether these services have been appropriately accounted for in its application.

The DUHS application assigns 0.25 FTEs for an Imaging Manager. The DUHS application fails to document how a 0.25 Imaging Manager can cover the full time operations of the freestanding center. There are certain basic staff positions, including an administrative manager, who must be physically present at the local center. Such staff are not adequately reflected in DUHS’s proposal and associated staffing costs are omitted, rendering the application nonconforming to Criterion 5. Moreover, it is unclear how DUHS will recruit a quarter FTE Imaging Manager, or how this person’s hours will be scheduled at the center.

It is also questionable why DUHS projects 1.62 FTEs for an MRI Technologist and 1.62 FTEs for a Clinical Nurse II in year 2. This does not adequately cover the MRI Technologist needs of

the freestanding center. A clinical nurse does not have the same training as an MRI technologist and cannot cover for the technologist position. While the MRI Criteria and Standards Staff and Staff Training Standards (10A NCAC 14C .2705) have been repealed, these standards required the availability of two full time MRI technologists and that one of these two technologists be present during the hours of operation of the MRI scanner. DUHS does not provide for two full-time MRI technologists with 1.62 FTEs. Even if the 0.25 MRI Imaging Manager is included as an MRI technologist in year 2, the combined total MRI technologist FTEs is 1.87 and does not demonstrate 2.0 full time FTEs available. From a minimum quality of care standpoint, DUHS does not appear to provide sufficient MRI technologist staff until the third year of operation.

DUHS Inconsistencies In Charity Care Projections Impacts Financial Feasibility.

On page 116 of its application, DUHS states that it will provide \$157,398, 7.13% of gross revenue, in charity care. However, this projection is wholly inconsistent with the pro forma projections. Form C shows that DUHS will have \$42,350 in self-pay gross revenue. Self-pay is generally the payor source classification for charity care patients. DUHS does not explain how it projects to provide almost four times the amount of charity care in comparison to its small self-pay projection. Further, the projected payor mix on page 124 of the applications shows just 1.9 percent of procedures will be self-pay patients. This inconsistency and low projection of charity care impacts DUHS's financial feasibility in that the reasonableness of its projections are questionable.

For all of these reasons, DUHS 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.

DUHS fails to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. As stated throughout its application, the proposed fixed MRI scanner will be used to serve DUHS patients. The existing DUHS MRI scanners have capacity to handle the projected growth in utilization, absent the added market share increase. As such, the proposed project would duplicate DUHS' existing MRI scanners in Wake County. Moreover, as is documented in the DUHS application, the proposal is focused on receiving referrals from DUHS-affiliated physicians. Outside of claiming that it will have a different charge structure, the proposed project simply duplicates the services currently offered by DUHS in a separate location.

As discussed in these comments, DUHS has not reasonably supported its utilization projections. Fundamental flaws exist in the DUHS methodology to project utilization. For instance, DUHS projects more than a 5% increase in MRI utilization for its own patients in its primary service area compared to the DUHS service area and Wake County projected population growth of 1% to 2% per year, which serves as the basis for DUHS' overall area-wide growth in demand. DUHS' projected growth in MRI volume is larger than the DUHS projected area-wide rate of population growth, which confirms that DUHS must take volume from existing MRI providers in the area. Given the capacity of these existing MRI scanners and DUHS' failure to discuss them in its application, DUHS has failed to demonstrate that its proposed project will not unnecessarily duplicate the existing and approved health service facilities in the service area.

For all these reasons, the DUHS 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.

DUHS 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, the DUHS application fails to sufficiently explain or otherwise document how all support services and staff will be provided and whether these services have been appropriately accounted for in the application. The DUHS application assigns 0.25 FTEs for an Imaging Manager. This is the only administrative personnel listed in the application. The DUHS application fails to document how a 0.25 Imaging Manager can cover the full time operations of a freestanding center. There are certain basic staff positions, including an administrative manager, who must be physically present at the local center. Such staff are not adequately proposed in DUHS' proposal, including associated staffing costs. Moreover, it is unclear how DUHS will recruit a quarter FTE Imaging Manager or how this person's hours will be scheduled.

It is also questionable why DUHS projects 1.62 FTEs for an MRI Technologist and 1.62 FTEs for a Clinical Nurse II. This staffing does not adequately cover the MRI Technologist needs of the freestanding center. A clinical nurse does not have the same training as an MRI Technologist and cannot cover for the technologist position.

Furthermore, the DUHS application proposed that the medical director of the new freestanding will be Mustafa R. Bashir, MD. Dr. Bashir is based at Duke University Medical Center in Durham, which is located over 30 miles from Holly Springs. It is unclear if, or when, Dr. Bashir will be able to serve as the medical director at the Holly Springs center.

For all of these reasons, the DUHS application should be found non-conforming with Criterion 7.

Criterion 8: The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

The DUHS application does not demonstrate that DUHS will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services, and thus did not demonstrate conformity with Criterion 8. In addition, DUHS fails to demonstrate that the proposed service will be coordinated with the existing health care system.

DUHS Does Not Adequately Provide for Necessary Support Services

In Section 2, page 16 of its application, DUHS lists a range of support services that will be provided by the existing DUHS system. This list is very broad and contains a wide range of services that will need to be provided locally within the actual imaging center. DUHS has not explained how staff from other locations within DUHS will provide such services to a new freestanding single modality imaging center located in an area where DUHS has no current

facility operational. It is not possible for DUHS to provide many of these services offsite. Unless DUHS has tremendous amounts of excess staff that it will move to the new location then the staff supporting many of these activities have not appropriately been covered. Even if this excess staff exists, which DUHS does not document in its application, DUHS has not adequately explained in its application from where such staff will be transferred or when and how the transfer will occur. The lack of description renders the ancillary and support services unreliable for the DUHS project.

In addition, even if these excess staff exist, when they begin working at the proposed MRI center, their salary and benefits should have been included in the project pro forma so that the financial feasibility of the project can be evaluated. The DUHS application did not include such salaries or benefits in its pro forma projections for the project.

Furthermore, as noted previously in these comments, the DUHS application's projection of 0.25 FTEs for administrative functions of the proposed Duke Radiology Holly Springs project is unreasonable. All administrative functions and supervision of a freestanding imaging center cannot be provided with .25 FTEs allocated to an Imaging Manager position.

Accordingly, under Criterion 8, DUHS had not demonstrated that it will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. For this reason, DUHS should be found non-confirming with Criterion 8.

DUHS Does Not Coordinate with the Existing Health Care System.

The DUHS application fails to demonstrate that the proposed service will be coordinated with the existing health care system. DUHS states throughout its application that the proposed fixed MRI will serve DUHS patients. Further evidence of DUHS's lack of coordinate are their letters of support. All but one of their letters of support were provided by DUHS-affiliated physicians, and that one letter was provided by a community organization – Project Access of Wake County. DUHS provided no letters from non-affiliated physician groups or non-affiliated hospitals. In contrast; Wake Radiology's application shows broad support for its proposed fixed MRI scanner. Wake Radiology provided letters of support from several practices with multiple different specialties. Wake Radiology also included letters from the chairman of the Franklin County Board of Commissioners, as well as the mayor and a council member for the Town of Louisburg, which is located in Franklin County. Further, Wake Radiology has an existing agreement with the Franklin County Health Department to provide services to some of their patients.

Criterion 12: Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

The DUHS application fails to demonstrate that the proposed project represents the most reasonable alternative under Criterion 12. DUHS's proposed project costs are extremely high for the addition of a fixed MRI scanner to a new freestanding single modality imaging center. This is in large part due to the fixed MRI scanner being located in a building that has yet to be

constructed and there are no other services that will share the project costs. DUHS' total capital costs are \$5,965,000. The proposed capital cost far exceeds average cost of acquiring a fixed MRI scanner. DUHS could have lower the capital cost requirements significantly by proposing to locate the fixed MRI scanner in an existing building or imaging center, which would make the proposed project far more cost-effective and a more efficient use of healthcare resources.

In addition, the DUHS application fails to provide a certified architect's construction cost letter. Section XI, Question 5 of the CON application form specifically requires the applicant to provide a construction cost estimate certified by a North Carolina licensed architect or engineer. The architect's letter serving as a construction cost estimate, provided in Exhibit 12 of the application, lacks a certification stamp, indicating that the project costs are not certified.

For all of these reasons, the DUHS application should be found non-conforming with Criterion 12.

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:

...

- 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; and***

The DUHS 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). DUHS will provide a very low level of access to the charity care patients. On page 116 of its application, DUHS states that it will provide \$157,398, 7.13% of gross revenue, in charity care. This projection is wholly inconsistent with the pro forma projections. Form C shows that DUHS will have \$42,350 in self-pay gross revenue. Self-pay is generally the payor source classification for charity care patients. DUHS does not explain how it projects to provide almost four times the amount of charity care in comparison to its small self-pay projection. Further, the projected payor mix on page 124 of the application shows just self-pay as only 1.9% of the payor mix.

The DUHS application also proposes to offer a relatively low percentage of care to Medicare and Medicaid patients. DUHS projects a payor mix of 27.4% Medicare and 5.2% Medicaid, a total of 32.6% combined. In particular, the Medicare percentage appears to be low for a service that is highly utilized by the senior population.

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

- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.*

The DUHS application fails to offer a range of means by which a person will have access to the MRI service, and is otherwise nonconforming with Criterion 13(d). As provided in the DUHS application, a patient must receive care from a DUHS-affiliated physician in order to utilize the proposed MRI service. In essence, there is only one means to access the service and not the range of means required by Criterion 13(d), with the exception of small number of charity patients that are Project Access enrollees. DUHS claims that it will serve Project Access enrollees but does not explain how it will serve these patients and how these patients will have access to the proposed MRI unit through the referrals of DUHS affiliated physicians.

Accordingly, the DUHS application should be found non-conforming with Criterion 13(d).

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.

As discussed previously in these comments addressing Criterion 1, DUHS' proposed fixed MRI scanner will not have a positive impact upon the cost effectiveness, quality, and access to the services proposed. DUHS' proposed project will not improve competition for MRI services in Wake County, and, if anything, the project will reduce competition. As stated above, and throughout its application, DUHS' proposal is that the proposed MRI scanner will only serve patients receiving care from DUHS-affiliated physicians. DUHS fails to discuss the MRI service landscape in Wake County, outside of discussion of its own system.

The proposal is not cost-effective and represents a highly costly way to add MRI capacity to Wake County. In fact, the proposed project is highly ineffective itself in terms of cost as discussed above in these comments.

As stated throughout these comments, the DUHS proposal will have a limited access to the underserved. In addition, the DUHS application provides inconsistent data regarding the proposed level of charity care it will provide. In contrast, Wake Radiology's proposed project will offer far greater access to the underserved. As discussed above in these comments, there are inconsistencies in the amount of charity care that DUHS projects to provide. As a result, the DUHS application has not adequately demonstrated the accessibility of its proposed MRI scanner in a manner to conform to Criterion 18a.

For all these reasons, the DUHS application should be found non-conforming with Criterion 18a.

DUHS Fails to Provide the Information Required of the CON Application Form

The Architect's Cost Letter is Deficient

DUHS fails to provide a certified architect's construction cost letter. Section XI, Question 5 of the CON application form specifically requires the applicant to provide a construction cost estimate certified by a North Carolina licensed architect or engineer. The architect's letter serving as a construction cost estimate, provided in Exhibit 12 of the application, lacks a certification stamp, indicating that the project costs are not certified.

DUHS Failed to Follow the Instructions for Submitting the Certificate of Need (CON) Application Form

Instruction 8 requires that all pages of the CON be page numbered, including the exhibits. DUHS failed to page number its exhibits. This error creates a hardship on the Agency and raises additional questions about whether the application is complete or could be missing pages.

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 with a new unit. The new unit will not bring a meaningful increase in capacity of MRI services. Notably, both Raleigh Radiology and Wake Radiology currently operate MRO scanners in Cary. Raleigh Radiology's project will not increase geographic access in Wake 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 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 applicants 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 letters 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 has 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 letters 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 than 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 expensive 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 scab 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.

* * * *

DUHS's project is not a cost effective use of almost \$6 million of resources to duplicate services already offered by DUHS for DUHS patients. DUHS has to capture significant market share growth in a new area to meet its projections. DUHS' project will have limited accessibility due its referrals from only DUHS affiliated physicians and its low projected care for underserved population. DUHS' project has insufficient staffing and questionable expense allocations raising issues of financial feasibility. DUHS' project is comparatively inferior to Wake Radiology in terms of enhancing geographic access and financial access. DUHS' application should be denied and Wake Radiology's application should be approved.