

May 31, 2016

Gloria Hale, Project Analyst
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603



RE: Comments on Wake County Fixed MRI CON Applications

Dear Ms. Hale:

Enclosed please find comments prepared by Duke University Health System regarding the competing CON applications for one fixed MRI scanner for Wake County, to meet the need identified in the *2016 State Medical Facilities Plan*. We trust that you will take these comments into consideration during your review of the applications.

If you have any questions about the information presented here, please feel free to contact me at (919) 668-0857. I look forward to seeing you at the public hearing.

Sincerely,

Catharine Cummer

Catharine Cummer
Regulatory Counsel, Strategic Planning

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

Submitted by Duke University Health System
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. In accordance with N.C.G.S. §131E-185(a.1)(1), this document includes comments relating to the representations made by the other applicants, and a discussion about whether the material in each application complies with the relevant review criteria, plans, and standards. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of an additional fixed MRI scanner in Wake County.

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

- (1) demonstrate conformity with applicable review criteria and rules,
- (2) improve geographic access to fixed MRI services in Wake County,
- (3) represent the most effective alternative for developing a fixed MRI program, with competitive charges and costs,
- (4) demonstrate improved access for the medically underserved, and
- (5) document support from local referring physicians.

The Agency typically performs a comparative analysis when evaluating competing fixed MRI applications in a need determination batch review. The purpose is to identify the applicant that would bring the greatest overall benefit to the community. The table below summarizes 10 objective metrics that the Agency should use for comparing the three applications in this Wake County MRI batch review.

It is important to note that the comparative analysis for costs is based on Project Year 3 for each of the applicants. This is the most reasonable comparison given that two of the applicants are existing providers, and Duke University Health System (DUHS) d/b/a Duke Radiology Holly Springs (DRHS) will be a new facility, with a volume ramp-up; thus Project Year 3 provides the most representative comparison.

Wake County Fixed MRI Applicant Comparative Analysis

| Metrics | | | |
|--|-----------|----------------------|-------------------|
| Comparative | DRHS | Raleigh Radiology | Wake Radiology |
| Conforming to All Review Criteria | Yes | No | No |
| Improve Geographic Access | Yes | No | Yes |
| PY3 Gross Revenue/Scan | \$ 1,052 | \$ 1,177 | \$ 2,184 |
| PY3 Net Revenue/Scan | \$ 534 | \$ 403 | \$ 525 |
| PY3 Operating Cost/Scan, excluding professional fees | \$ 400 | \$ 227 | \$ 597 |
| Reimbursement/Cost Ratio | 1.34 | 1.77 | 1.44 |
| Self-Pay/Charity Care % | 1.9% | 5.8% | 1.9% |
| Medicare % | 27.4% | 30.5% | 38.2% |
| Medicaid % | 5.2% | 2.0% | 6.3% |
| Wake County Patient Origin % | 88.0% | 84.3% | 58.1% |
| PY2 MRI Tech Salary | \$ 76,879 | \$ 73,847 | \$ 81,482 |

| Rankings | | | |
|--|-------------|----------------------|-------------------|
| Comparative | DRHS | Raleigh Radiology | Wake Radiology |
| Conforming to All Review Criteria | 1 | 2 | 2 |
| Improve Geographic Access | 1 | 2 | 1 |
| PY3 Gross Revenue/Scan | 1 | 2 | 3 |
| PY3 Net Revenue/Scan | 3 | 1 | 2 |
| PY3 Operating Cost/Scan, excluding professional fees | 2 | 1 | 3 |
| Reimbursement/Cost Ratio | 1 | 3 | 2 |
| Self-Pay/Charity Care % | 2 | 1 | 2 |
| Medicare % | 3 | 2 | 1 |
| Medicaid % | 2 | 3 | 1 |
| Wake County Patient Origin % | 1 | 2 | 3 |
| PY2 MRI Tech Salary | 2 | 3 | 1 |
| Average | 1.7 | 2.0 | 1.9 |
| Total | 19.0 | 22.0 | 21.0 |

For each of the comparative metrics shown in the first table, DRHS ranked the providers in terms of effectiveness, as shown in the second table. A rank of "1" indicates the most effective applicant, with "3" indicating the least effective of the three applications. As the second table portrays objectively, the DRHS application is the most effective alternative because DRHS offers the lowest total and average scores. In other words, the Agency will enable the greatest overall benefit to local residents by approving the DRHS application. Specifically:

- DRHS is the only applicant conforming to all applicable regulatory review criteria. Wake Radiology is nonconforming to several regulatory review criteria and, most notably, administrative rule 10A NCAC 14C .2703(b)(2) applicable for the review of fixed MRI scanners. Raleigh Radiology proposes unreasonable payor mix and utilization projections and is nonconforming to Review Criteria 3 and 13c, among others.
- Raleigh Radiology proposes to locate the fixed MRI scanner in Cary. As described in DRHS CON application on page 40, there are already two fixed MRI scanners located in Cary. Raleigh Radiology, moreover, proposes to replace a full-time scanner operated by Alliance Imaging with a fixed scanner in the same location. Therefore, there is no geographic benefit or increased access achieved by the Raleigh Radiology proposal. Wake Radiology proposes to develop a fixed MRI scanner in Wake Forest. While Wake Forest does not currently host a fixed MRI scanner, as shown in the following table, there is a comparatively larger underserved population in Apex/Holly Springs compared to Wake Forest.

Wake County Fixed MRI Scanners by Location

| Area | 2014 Pop | Fixed MRI Scanners | Population/ Fixed MRI Scanner |
|--------------------|----------|--------------------|----------------------------------|
| Cary (Town) | 155,227 | 2 | 77,614 |
| Raleigh | 439,896 | 13 | 33,838 |
| Garner (Town) | 27,814 | 1 | 27,814 |
| Apex/Holly Springs | 74,064 | 0 | |
| Wake Forest | 36,693 | 0 | |
| Morrisville | 22,772 | 0 | |
| Knightdale/Wendell | 20,053 | 0 | |
| Wake County | 998,691 | 16 | 62,418 |

Source: US Census Bureau, 2016 SMFP

Therefore, the DRHS proposal provides the greatest benefit to Wake County residents from the perspective of improved geographic access.

- DRHS proposes reasonable charges for its fixed MRI scanner in Wake County, and projects the lowest gross revenue per scan of the competing applicants. The DRHS MRI service will have a different charge structure from the existing DUHS hospital-based fixed MRI services in Wake County. This may offer individuals who may have no insurance, high deductible or co-insurance plans a potentially lower cost alternative without sacrificing quality of service. Wake Radiology projects the highest gross revenue/scan.
- DRHS proposes market-competitive operating costs for a new fixed scanner. DRHS offers a modest operating cost/scan in the third project year, even though as a new provider it is still in the “ramp-up” phase of offering services. Its operating cost/scan will only become even more competitive beyond the initial three project years.
- DRHS proposes the lowest reimbursement-to-cost ratio. Raleigh Radiology projects the highest reimbursement-to-cost ratio, which is an indication of generous revenue projections consistent with a for-profit provider.
- Raleigh Radiology projects unreasonably high charity care, Medicare, and Medicaid projections that are inconsistent with their historical payor mix for MRI services. Wake Radiology provided no historical data to substantiate the reasonableness of their payor mix projections. DRHS projects reasonable charity care, Medicare, and Medicaid payor mix based on historical experience.
- The SMFP MRI need determination is for Wake County; therefore, access for Wake County residents is paramount. DRHS projects the highest Wake County patient origin percentage of the competing applications.
- In recruitment and retention of personnel, salaries are a significant factor. DRHS projects the highest salary for MRI technologists. Therefore, DUHS is the most effective alternative with regard to clinical staff salaries.

Specific comments regarding the Raleigh Radiology, LLC application

- Raleigh Radiology's projected MRI procedures are overly aggressive and unrealistic. On page 96 of Raleigh Radiology's CON application it states, *"Using the 20.5 percent annual growth rate to forecast the future is reasonable."* However, a 20.5 percent growth rate is, in fact, unreasonable for projecting future MRI procedure volume for an existing facility that already offers full-time MRI services. As shown in the following table, Raleigh Radiology's procedure growth has diminished in the most recent year.

Raleigh Radiology Cary – MRI Procedures

| | 2013 | 2014 | 2015 |
|----------------|-------|-------|-------|
| MRI Procedures | 3,827 | 4,677 | 5,559 |
| Annual Growth | -- | 22.2% | 18.9% |

Source: Raleigh Radiology CON application, page 95

As shown in the previous table, RRCary's procedure growth was lower in 2015 compared to 2014. This is consistent with diminishing returns which can be expected after a facility experiences a ramp-up in utilization. Specifically, RRCary's MRI volume increased subsequent to the implementation of full-time MRI access via Alliance's parked MRI scanner. As a result, RRC experienced an increase in MRI volume during the following years. However, as shown by 2015 MRI volume, RRC's procedure growth has already begun to diminish. Raleigh Radiology's application of a 20.5% growth rate is inconsistent with the diminishing growth rate the facility has already exhibited.

Raleigh Radiology's projection methodology applies an annual 20.5% growth rate to RRCary procedure volume until the proposed fixed MRI scanner reaches 100% capacity. This rationale is not supported based on utilization data for Raleigh Radiology Cedarhurst. On page 98 of Raleigh Radiology's CON application, the applicant projects RRC will reach capacity shortly after opening. The applicant states, *"Raleigh Radiology Cedarhurst's MRI volumes suggest the applicant's utilization projections are entirely reasonable."* However, Raleigh Radiology Cedarhurst's MRI volumes prove that RRCary's projected procedure volumes are not reasonable and instead are unrealistic. Specifically, Raleigh Radiology Cedarhurst's 2016 Registration and Inventory of Medical Equipment Form indicates on page 2 that the fixed MRI scanner was operational for 4,020 hours during the

reporting period. Therefore, the total capacity of the Raleigh Radiology Cedarhurst's MRI scanner was 8,040 (4,020 total hours × 2 MRI procedures per hour). Page 2 of Raleigh Radiology Cedarhurst's 2016 Registration and Inventory of Medical Equipment Form indicates the fixed MRI scanner performed a total of 6,748 MRI procedures during FY2015 or 83.9% capacity (6,748 ÷ 8,040). Raleigh Radiology states on page 97 that the proposed fixed MRI scanner at RRCary has a maximum capacity of 8,046 procedures, which is nearly equivalent to Raleigh Radiology Cedarhurst's MRI scanner. The projected utilization of 100% of fixed MRI capacity at RRCary is in no way supported by Raleigh Radiology Cedarhurst's fixed MRI utilization.

In summary, Raleigh Radiology failed to demonstrated projected procedure volume is based on reasonable and supported assumptions. Therefore, the proposal is nonconforming to Criterion 3.

- Raleigh Radiology failed to demonstrate the projected utilization at RRCary is appropriate for the proposed 3.0T MRI scanner. DUHS currently owns and operates a 3.0T fixed MRI scanner at Duke University Hospital (DUH). Therefore, DUHS is knowledgeable regarding the types of patients that are appropriate for 3.0T MRI scanners. In fact, several types of patients are not appropriate for a 3.0T MRI scanner, including:
 - patients with implanted metallic devices (particularly near the imaged anatomy),
 - patients who have had prior surgery in or near the imaged anatomy (prior rotator cuff surgery, cholecystectomy clips, sternal wires, etc.)
 - abdominal MRI in patients with ascites,
 - patients with implantable devices which are approved for use in 1.5T systems but not for use in 3T systems (such as some new pacemakers)
 - Elevated specific absorption rate (SAR) means extra safety precautions must be taken by the imaging team to monitor and terminate the study when SAR limits have been reached,
 - 3T systems generate a lot more noise than a 1.5T system, which some patients may find intolerable, and
 - unknown risks to pregnant patients - and pregnant staff (theoretically increased risk at 3T given the higher SAR and noise at 3T)

Raleigh Radiology failed to address any of the previously described indications for which their proposed 3.0T fixed MRI scanner will not be appropriate for projected patients. More importantly, Raleigh Radiology

failed to factor these patient types into their projection methodology and reduce their utilization projections accordingly. Therefore, Raleigh Radiology's projected MRI procedures are overly aggressive and unrealistic and the application is nonconforming to Criterion 3.

- Raleigh Radiology proposes to locate the fixed MRI scanner in Cary. As described in DRHS CON application on page 40, there are already two fixed MRI scanners located in Cary. The 2016 SMFP identifies the presence of 16 fixed MRI scanners in Wake County. The following table identifies the location of the existing and approved fixed MRI scanners in Wake County.

Wake County Fixed MRI Scanners by Location

| Area | 2014 Pop | Fixed MRI Scanners | Population/ Fixed MRI Scanner |
|--------------------|-----------|--------------------|----------------------------------|
| Cary (Town) | 155,227 | 2 | 77,614 |
| Raleigh | 439,896 | 13 | 33,838 |
| Garner (Town) | 27,814 | 1 | 27,814 |
| Apex/Holly Springs | 74,064 | 0 | |
| Wake Forest | 36,693 | 0 | |
| Morrisville | 22,772 | 0 | |
| Knightdale/Wendell | 20,053 | 0 | |
| | | | |
| Wake County | 998,691 | 16 | 62,418 |
| North Carolina | 9,943,964 | 233 | 42,678 |

Source: US Census Bureau, 2016 SMFP

Thirteen fixed MRI scanners are located in Raleigh, two are located in Cary, and one is located in Garner. There are no fixed MRI scanners located in Apex or Holly Springs. Therefore, the Raleigh Radiology proposal provides no benefit to Wake County residents from the perspective of geographic access.

- Raleigh Radiology's Cary office is currently an existing MRI location in Wake County, and thus the Raleigh Radiology proposal provides no benefit to Wake County residents from the perspective of geographic

access. The Raleigh Radiology application is not the most effective alternative from an access perspective.

- Raleigh Radiology did not adequately demonstrate the availability of funds for the capital needs of the project. Specifically, Raleigh Radiology failed to include a calculation of North Carolina sales tax on the capital equipment it proposes to purchase. As shown in the ownership table in Section I.10, Raleigh Radiology, LLC is a proprietary company and is not exempt from paying state income tax. Based on the total equipment cost of \$2,502,423 listed in Table VIII.2, the 6.75% sales tax that should be reflected in the Raleigh Radiology project capital cost is \$168,914. When added to the capital cost of \$2,922,552 listed by Raleigh Radiology on page 137, the total project capital cost should be \$3,091,466. Therefore, the project capital cost listed on page 137 does not include all necessary costs to acquire and make operational the proposed equipment, and therefore the application is non-conforming to Review Criterion 5. The Agency has previously found (Project ID P-8332-09) an MRI applicant to be non-conforming to Criterion 5 due to omission of sales tax from the project capital cost.

- Raleigh Radiology further did not adequately demonstrate the availability of funds for the capital needs of the project. Specifically, the bank funding letter is not accurate, and its validity is dubious. Exhibit 32 includes a letter purporting to evidence financing for the CON project. However, the letter itself raises red flags regarding its accuracy and validity.
 - First, in the second paragraph the letter listed the “fixed and working capital costs to be \$2,922,552”. This is an error, as per pages 137 and 143 of the application, Raleigh Radiology portrays the combined capital and working capital total as \$2,954,275. Further, as detailed in the previous bullet point, Raleigh Radiology’s exclusion of the sales tax calculation results in a further error of \$168,914. Therefore, the total combined funding need is actually \$3,123,189, or \$200,637 more than the letter indicates.
 - Second, in the second sentence of the second paragraph, the amount of available financing looks to have been erased and replaced with a new number (\$3,500,000). Clearly, this letter was revised, and the question then becomes who revised it, when, and

is Wells Fargo aware of the revision. Or is Wells Fargo willing to fund only a lesser, inadequate amount and someone changed the letter to increase the funding amount.

- Third, the letter is printed on letterhead of a Barbara Miller at Wells Fargo, but is not signed by Barbara Miller, but by a different, unknown person.

All of these discrepancies raise legitimate concerns about the availability of funds for the project, and therefore, Raleigh Radiology's application is nonconforming to Review Criterion 5, and is not approvable.

- The Raleigh Radiology loan amortization table shown in Exhibit 14 is inaccurate, as it does not reflect the loan amount needed. Per the discussion in the previous bullets, Raleigh Radiology needs a loan of \$3,123,189, but the amortization table reflects only a loan amount of \$2,922,552. This \$200,637 discrepancy would result in a higher loan principle, more loan interest, and therefore, higher monthly loan payments than Raleigh Radiology reflects in its application proforma income statement. Therefore, Raleigh Radiology did not demonstrate financial feasibility because it did not reasonably project the cost for providing the proposed health service, and should be found nonconforming to Review Criterion 5.
- Raleigh Radiology's projected MRI payor mix at RRCary is significantly different from the current MRI payor mix at the same site. The table on the following page compares Raleigh Radiology's actual MRI payor mix at RRCary during FY2015 compared to its projected MRI payor mix at RRCary.

RRCary Actual vs. Projected MRI Payor Mix

| Payor Mix Year 2 | Actual MRI Payor Mix | Proposed MRI Payor Mix | % Difference |
|---------------------------|-----------------------------|-------------------------------|---------------------|
| Self-Pay/ Charity Care | 1.0% | 5.8% | 480.0% |
| Medicare | 23.0% | 30.5% | 32.6% |
| Medicaid | 1.0% | 2.0% | 100.0% |
| Total | 25.0% | 33.8% | 53.2% |

Source: Raleigh Radiology CON Application, Section VI pages 119-120

Raleigh Radiology proposes a dramatic change in the MRI payor mix at RRCary, with self-pay/charity/indigent projected to increase 580%, Medicare projected to increase 33%, and Medicaid projected to increase 200% higher than the current actual payor mix. These are enormous payor mix changes, and are completely unreasonable considering Raleigh Radiology is proposing to continue to offer the same MRI service at the same location. The unreasonableness is reinforced by the fact that Raleigh Radiology projects no payor mix change for non-MRI procedures at RRCary. As stated on page 120, Raleigh Radiology "assumes existing payor mix for all other imaging services offered at RRCary will remain constant". Raleigh Radiology's attempted justification for this dramatic projected MRI payor mix change is inadequate. Rather, Raleigh Radiology's appears to have manufactured a new MRI payor mix for RRCary in order to gain CON approval from the Agency in this competitive batch review. The bottom line is, Raleigh Radiology's application is nonconforming to Review Criterion 13c because Raleigh Radiology did not adequately identify the extent to which the elderly and the medically underserved groups are expected to utilize the applicant's proposed service.

- Raleigh Radiology unreasonably projects a 580% increase in charity care. Last year, Raleigh Radiology states it provided \$73,876, or 1.0% charity care for MRI services at RRCary (page 113). On page 114, Raleigh

Radiology projects its charity care total to skyrocket to \$570,618, or 5.8% by PY2. This again appears to be a paper project not based on Raleigh Radiology's actual history of providing charity care, but rather on Raleigh Radiology's desire to gain Agency CON approval in a competitive MRI batch review. At any rate, Raleigh Radiology's projected charity care of 5.8% in PY2 is lower than the DRHS charity care projection of 7.13%. Therefore, Raleigh Radiology's application is not the most effective alternative for providing access to the medically indigent.

- Raleigh Radiology projects a lower projected Wake County patient origin of any applicant, as shown in the table below. Thus, Raleigh Radiology's proposal is a less effective alternative from an access perspective.

Projected Wake County Patient Origin, PY2

| DRHS | Raleigh Radiology |
|-------|-------------------|
| 88.0% | 84.3% |

Source: CON applications, Section III.5.

- Raleigh Radiology proposes higher charges than DRHS for all three project years. In the current healthcare marketplace, where cost of care is a major concern with payers and the public, the projected average procedure charge is an important measure of consumer value. Therefore, Raleigh Radiology's application is a less effective alternative.

Proposed Average Charge per Procedure*

| | DRHS | Raleigh Radiology |
|----------------|---------|-------------------|
| Project Year 1 | \$1,053 | \$1,250 |
| Project Year 2 | \$1,053 | \$1,213 |
| Project Year 3 | \$1,052 | \$1,177 |

*Reflects only technical charges, PY1-3

- Raleigh Radiology projects inadequate staff levels to cover its projected hours of operation. Specifically, on page 128 Raleigh Radiology's staffing table VII.2 shows the MRI Tech Assistant staffing requirement to be 52 hours/week. Multiplied by 50 weeks/year and reflecting adequate coverage for vacation, sick time, etc. Raleigh Radiology needs 1.44 FTE MRI Tech Assistants in PY2 ($52 \times 50 = 2,600$ hours/ $2,080 = 1.25 \times 115\% = 1.44$). Yet Raleigh Radiology shows only 1.42 FTEs in table VII.1a on page 124.

Similarly, Raleigh Radiology projects inadequate supervisor staff to cover the projected hours of staffing. Specifically, on page 128 Raleigh Radiology's staffing table VII.2 shows the MRI Supervisor staffing requirement to be 40 hours/week. Multiplied by 50 weeks/year and reflecting adequate coverage for vacation, sick time, etc. Raleigh Radiology needs 1.11 FTE MRI Supervisor in PY2 ($40 \times 50 = 2,000$ hours/ $2,080 = 0.96 \times 115\% = 1.11$). Yet Raleigh Radiology shows only 1.09 FTEs in table VII.1a on page 124.

Finally, and most importantly, Raleigh Radiology projects inadequate MRI Tech staff to cover the projected hours of operation. Specifically, on page 128 Raleigh Radiology's staffing table VII.2 shows the MRI Technologist staffing requirement to be 95 hours/week. Multiplied by 50 weeks/year and reflecting adequate coverage for vacation, sick time, etc. Raleigh Radiology needs 2.63 FTE MRI Technologists in PY2 ($95 \times 50 = 4,750$ hours/ $2,080 = 2.28 \times 115\% = 2.63$). Yet Raleigh Radiology shows only 2.60 FTEs in table VII.1a on page 124.

Therefore, Raleigh Radiology's application is nonconforming to Review Criterion 7 because Raleigh Radiology does not show evidence of the availability of health manpower for the provision of the services proposed. Raleigh Radiology's application is also non-conforming to Review Criterion 5 because Raleigh Radiology does not reasonably project the costs for providing services proposed.

- Salaries are a significant contributing factor in recruitment and retention of quality clinical staff, and therefore, from a quality of care perspective, represent a significant comparative metric for this CON batch review. Please see the following table.

**Projected MRI Technologist Salaries
Project Year 2**

| Applicant | Salary |
|-------------------|---------------|
| Wake Radiology | \$81,482 |
| DRHS | \$76,879 |
| Raleigh Radiology | \$75,169 |

DRHS projects the second highest MRI Tech salary per FTE. Therefore, Raleigh Radiology is the least effective alternative with regard to payments for MRI Technologists.

Specific comments regarding the Wake Radiology application

- Wake Radiology does not conform to the rules applicable for the review of fixed MRI scanners. Specifically, 10A NCAC 14C .2703(b)(2) states: *“demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data”*. Wake Radiology’s response to 10A NCAC 14C .2703(b)(2) on page 29 of its CON application states there were only 2,124 weighted MRI procedures performed on its mobile MRI scanner during April 1, 2015 through March 31, 2016. This is obviously below the 3,328 weighted MRI performance standard. Therefore, Wake Radiology is nonconforming to this rule and cannot be approved.
- Wake Radiology provides conflicting projections for its proposed fixed MRI scanner in Wake Forest. On page 50 of its CON application, Wake Radiology projects in Exhibit 24 that the WFO MRI Total is 4,505 weighted MRI procedures YE 6/30/2020. Notably, this is below the 10A NCAC 14C .2703 (b)(4) performance standard of 4,805 weighted MRI procedures. Furthermore, the “Wake Forest Baseline” and “Franklin County In-migration” projections in Exhibit 24 (page 50) are different from the projections with the same descriptions in Exhibit 6 (page 30). Wake Radiology provides no explanation for the difference in utilization projections nor does it identify which projections are correct. Therefore, the application should be found nonconforming to Criterion 3.
- Wake Radiology’s methodology described in Section III.1 utilizes aggressive and unrealistic growth projections. On page 48, Wake Radiology utilized an annual growth rate of 31.35% to project baseline growth in weighted MRI procedures at the Wake Forest Office. In addition, Wake Radiology assumes an additional 8% growth in year one of the proposed fixed MRI scanner. Wake Radiology failed to provide any specific rationale to support 1) why the double-digit growth will persist during the next four years, and 2) why it is reasonable to include an

additional 8% growth simply because it will offer fixed MRI services instead of mobile MRI services at the same location.

Wake Radiology also rationalizes the need for the proposed Wake Forest fixed MRI scanner based on access for Franklin County residents. Wake Radiology's projected utilization by Franklin County residents is grossly overstated. Novant Health Franklin Medical Center (NHFMC) closed in October 2015. According to their 2016 license renewal application, NHFMC performed only 581 outpatient MRI procedures (624 weighted outpatient MRI procedures) during FY2015. On page 49 of Wake Radiology's CON application, the applicant incorrectly stated NHFMC's MRI procedure volume during FY2015 was 1,069 weighted MRI procedures. The 2016 license renewal application was publically available to Wake Radiology at the time the CON application was submitted on April 15, 2016; therefore, the applicant could and should have utilized the most recent and accurate MRI data for NHFMC. Instead, Wake Radiology used an assumption that is not representative of actual MRI use at NHFMC. Therefore, Wake Radiology's weighted MRI procedures based on projected Franklin County In-migration are overstated.

Finally, Wake Radiology failed to demonstrate the utilization for its four existing fixed MRI scanners is based on reasonable and supported assumptions. Wake Radiology projected weighted MRI procedures based on the aggregate volume for its four existing fixed MRI scanners. As shown in Exhibit 20 (page 48), Wake Radiology has experienced a significant decrease in MRI procedures at its Raleigh location, i.e., the location at which the greatest number of procedures are provided for Wake Radiology. The decrease in utilization at WRDI Raleigh between FY2013 and FY2015 is in contrast to a 7.26% increase in the total number of unweighted MRI procedures performed in Wake County at all locations, including WRDI Raleigh, between FY2015 and FY2020. The applicants do not adequately explain this decrease in their application.

In summary, Wake Radiology did not adequately demonstrate that projected utilization of the proposed fixed MRI scanner at the Wake Forest Office, the four existing fixed MRI scanners or the existing mobile MRI scanner owned by Wake Radiology are based on reasonable and supported assumptions. Consequently, the applicants did not adequately demonstrate the need the population to be served has for the proposed

fixed MRI scanner. Therefore, Wake Radiology is nonconforming to Criterion 3.

- Wake Radiology's Wake Forest office is currently an existing MRI location in Wake County, and thus the Wake Radiology proposal provides no benefit to Wake County residents from the perspective of geographic access. The Wake Radiology application is not the most effective alternative from an access perspective.
- Wake Radiology projects by far the lowest projected Wake County patient origin of any applicant, as shown in the table below. Thus, Wake Radiology's proposal is the least effective alternative from an access perspective.

Projected Wake County Patient Origin, PY2

| DRHS | Raleigh Radiology | Wake Radiology |
|-------|-------------------|----------------|
| 88.0% | 84.3% | 58.1% |

- Another issue to consider when evaluating the competing applications is the extent to which each proposed project represents a cost-effective alternative for provision of MRI services. In the current healthcare marketplace, where cost of care is a major concern with payers and the public, the projected average procedure charge is an important measure of consumer value. DRHS proposes lower charges and lower costs than Wake Radiology for all three project years.

Proposed Average Charge per Procedure*

| | DRHS | Wake Radiology |
|----------------|---------|----------------|
| Project Year 1 | \$1,053 | \$2,184 |
| Project Year 2 | \$1,053 | \$2,184 |
| Project Year 3 | \$1,052 | \$2,184 |

Proposed Average Cost per Procedure*

| | DRHS | Wake Radiology |
|-----------------------|--------------|-----------------------|
| Project Year 1 | \$554 | \$690 |
| Project Year 2 | \$485 | \$632 |
| Project Year 3 | \$400 | \$597 |

*Reflects only technical charges, PY1-3

In fact, Wake Radiology projects the highest charges and costs of any applicant, and is therefore, the least effective alternative.

- Wake Radiology's projected charity care of 4.0% in PY2 is lower than the DRHS charity care projection of 7.13%, and thus represents a less effective alternative in terms of providing access for the medically indigent population of Wake County.
- Wake Radiology chooses not to provide its historical MRI payor mix at its Wake Forest location, ostensibly in order to "project" a more favorable payor mix in order to attempt to gain CON approval in a competitive batch review. In its application, Wake Radiology does not answer questions VI.12 and VI.13 seeking the current payor mix at the facility and for the MRI service at the Wake Forest location, claiming it need not provide this information because it provides mobile MRI services rather than fixed MRI services. The basis for this non-responsive answer is specious. Instead, Wake Radiology uses the "not applicable" response as cover for an entirely new projected MRI payor mix. Wake Radiology does not provide any basis for or justification of its projected Medicare payor mix of 38.2% or of its projected Medicaid payor mix of 6.3%. Wake Radiology appears to have manufactured a new MRI payor mix for its Wake Forest location in order to gain CON approval from the Agency in this competitive batch review.
- Wake Radiology did not adequately demonstrate the availability of funds for the capital needs of the project. Specifically, Wake Radiology failed to include a calculation of North Carolina sales tax on the capital equipment

it proposes to purchase. As shown in the ownership table in Section I.10, Wake Radiology Services, LLC is a proprietary company and is not exempt from paying state income tax. Based on the total equipment cost of \$1,402,792 listed in Table VIII.2, the 6.75% sales tax that should be reflected in the Wake Radiology project capital cost is \$94,688. When added to the capital cost of \$1,779,992 listed by Wake Radiology on page 89, the total project capital cost should be \$1,874,680. Therefore, the project capital cost listed on page 89 does not include all necessary costs to acquire and make operational the proposed equipment, and therefore the application is non-conforming to Review Criterion 5. The Agency has previously found (Project ID P-8332-09) an MRI applicant to be non-conforming to Criterion 5 due to omission of sales tax from the project capital cost.

- The Wake Radiology loan amortization table shown in Exhibit 14 is inaccurate, as it does not reflect the loan amount needed. Per the discussion in the previous bullets, Wake Radiology needs a loan of \$1,874,680, but the amortization table reflects only a loan amount of \$1,779,992. This \$94,688 discrepancy would result in a higher loan principle, more loan interest, and therefore, higher monthly loan payments than Wake Radiology reflects in its application proforma income statement. Therefore, Wake Radiology did not demonstrate financial feasibility because it did not reasonably project the cost for providing the proposed health service, and should be found non-conforming to Review Criterion 5.
- The amortization table included in Attachment Q inaccurately reflects the assumed loan interest rate. Per the funding letter in Attachment P, "the loan will be repaid based on a 5-year amortization (60 payments) at an interest rate of LIBOR plus 155 basis points". 155 basis points means 1.55% higher than the LIBOR rate. However, in the Wake Radiology amortization table, Wake Radiology incorrectly lists the interest rate based on adding 0.155% to LIBOR. This results in a significant interest rate difference of 1.40%. On a loan of \$1,874,680, that results in incremental interest of over \$67,000. Therefore, Wake Radiology did not demonstrate financial feasibility because it did not reasonably project the cost for

providing the proposed health service, and should be found non-conforming to Review Criterion 5.

- Wake Radiology proposes only MRI Technologists, and no other clinical staffing, unlike the competitors who propose nurses or MRI Tech Assistants to supplement the MRI Technologist. Therefore, Wake Radiology is the least effective alternative vis-à-vis staffing size for highest quality of care.