



May 28, 2021

Gregory Yakaboski, 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 regarding competing Wake County Fixed MRI Scanner CON Applications

Dear Mr. Yakaboski:

Enclosed please find comments prepared by Pinnacle Health Services of North Carolina regarding the competing CON applications to develop one fixed MRI scanner within Wake County, to meet the need identified in the *2021 State Medical Facilities Plan*. We appreciate your consideration of these comments during your review of the applications.

If you have any questions about the information presented here, please contact me at 919.877.5428.

Sincerely,

Amber George

Amber George
Administrator

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

**Submitted by Pinnacle Health Services of North Carolina
May 31, 2021**

Three applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2021 State Medical Facilities Plan (SMFP)* for one additional fixed MRI scanner in Wake County. These include:

- J-12063-21 Pinnacle Health Services of North Carolina, LLC d/b/a Cardinal Points Imaging of the Carolinas
- J-12068-21 WR Imaging, LLC & Wake Radiology Diagnostic Imaging, Inc. d/b/a Wake Radiology Garner
- J-12073-21 Duke University Health System, Inc. d/b/a Duke Imaging North Raleigh

In accordance with N.C.G.S. §131E-185(a.1)(1), PHSNC submits these written comments addressing representations in the competing applications, and a discussion about whether the information in the competing applications complies with the Certificate of Need review criteria. These comments also address the issue of which competing proposal represents the comparatively most effective alternative for development of an additional fixed MRI scanner in Wake County. These written comments are not intended to include any additional information that would represent an amendment to PHSNC's own CON application.

The Agency usually performs a comparative analysis when evaluating competing fixed MRI scanner applications in a need determination batch review. The purpose is to identify the applicant that would bring the greatest overall benefit to the county community. The table on the following page summarizes standard metrics that the Agency has typically used for comparing applications in a county fixed MRI scanner batch review.

2021 Wake County Fixed MRI Scanner Review CON Application Comparative Analysis

	PHSNC	DUHS	Wake Radiology
Conformity with Review Criteria & Administrative Rules	Yes	No	No
Scope of Services	Equally Effective	Not Approvable	Not Approvable
Competition (Access to New Provider)	Equally Effective	Not Approvable	Not Approvable
Ownership of Fixed MRI Scanners in County	Most Effective	Not Approvable	Not Approvable
Access by Service Area Residents	Effective	Not Approvable	Not Approvable
Geographic Accessibility	Most Effective	Not Approvable	Not Approvable
Access by Charity Care	Most Effective	Not Approvable	Not Approvable
Access by Medicare	Effective	Not Approvable	Not Approvable
Access by Medicaid	Effective	Not Approvable	Not Approvable
Projected Average Net Revenue per MRI procedure	Most Effective	Not Approvable	Not Approvable
Projected Average Operating Expense per MRI procedure	Most Effective	Not Approvable	Not Approvable

As the table objectively portrays, aside from being the only approvable application, the PHSNC application is overall the most effective alternative. In other words, the Agency will enable the greatest benefit to local residents by approving the PHSNC application. Specifically:

- **Conformity with Review Criteria.** The PHSNC application is conforming to all CON review criteria. In contrast, the DUHS and Wake Radiology applications both fail to conform to multiple review criteria and to the MRI administrative rules: neither application is approvable.
- **Ownership of Fixed MRI Scanners in Wake County.** According to the 2021 SMFP, 19 fixed MRI scanners currently operate -- or are approved for development -- in Wake County. DUHS owns and operates three fixed MRI scanners in Wake County, and the members of WR Imaging (Wake Radiology and UNC Rex) own and operate a combined five fixed MRI scanners in Wake County. Thus, between them, DUHS and the members of WR Imaging currently control eight of the 19 existing and approved fixed MRI scanners in Wake County. Control of 42% of the Wake County fixed MRI scanner inventory represents a dominant position in the marketplace between these providers, and the Agency should seek to improve the competitive balance within the marketplace via this fixed MRI scanner review. By contrast, PHSNC operates one fixed MRI scanner (at its CPIC Midtown location), which represents just 5% of the Wake County fixed MRI scanner inventory. Competition in the Wake County marketplace will be enhanced with approval of PHSNC for a second fixed MRI scanner, while approval of either DUHS or Wake Radiology will not have a positive effect on MRI competition.
- **Access by Service Area Residents.** The following table shows the projected Wake County patient origin percentage of the competing applications. However, neither the DUHS nor the Wake Radiology applications are conforming to all statutory review criteria and to the MRI administrative rules, and therefore are not approvable.

Projected Wake County Patient Origin, PY3

PHSNC	DUHS	Wake Radiology
62.0%	66.0%	55.4%

Source: CON applications, Section C.3.

- Increase Geographic Accessibility.** DUHS proposes to locate a fixed MRI scanner in Raleigh (on the campus of Duke Raleigh Hospital, where DUHS currently owns and operates two fixed MRI scanners), and Wake Radiology proposes to locate a fixed scanner in Garner, at the facility where it currently already offers fixed MRI services. Both applicants are proposing to place a fixed MRI scanner in a location already served by a fixed scanner. As described on page 41 of the PHSNC CON application, 13 fixed MRI scanners are located in Raleigh, and Garner also currently hosts a fixed MRI scanner. Approval of either the DUHS or the Wake Radiology proposal would establish a 15th fixed scanner in Raleigh/Garner, which would represent 75% (15/20) of the Wake County total fixed MRI scanner inventory. The population/scanner ratios for both Raleigh and Garner are lower than for Wake County overall. There is no enhanced geographic benefit achieved by either of the DUHS or Wake Radiology proposals. In sharp contrast, PHSNC proposes to develop a fixed MRI scanner in Wake Forest, a community that does not currently host a fixed MRI scanner. As the following table portrays, the Wake Forest/Rolesville area is the largest population center in Wake County that does not host a fixed MRI scanner, and is more populous than Garner.

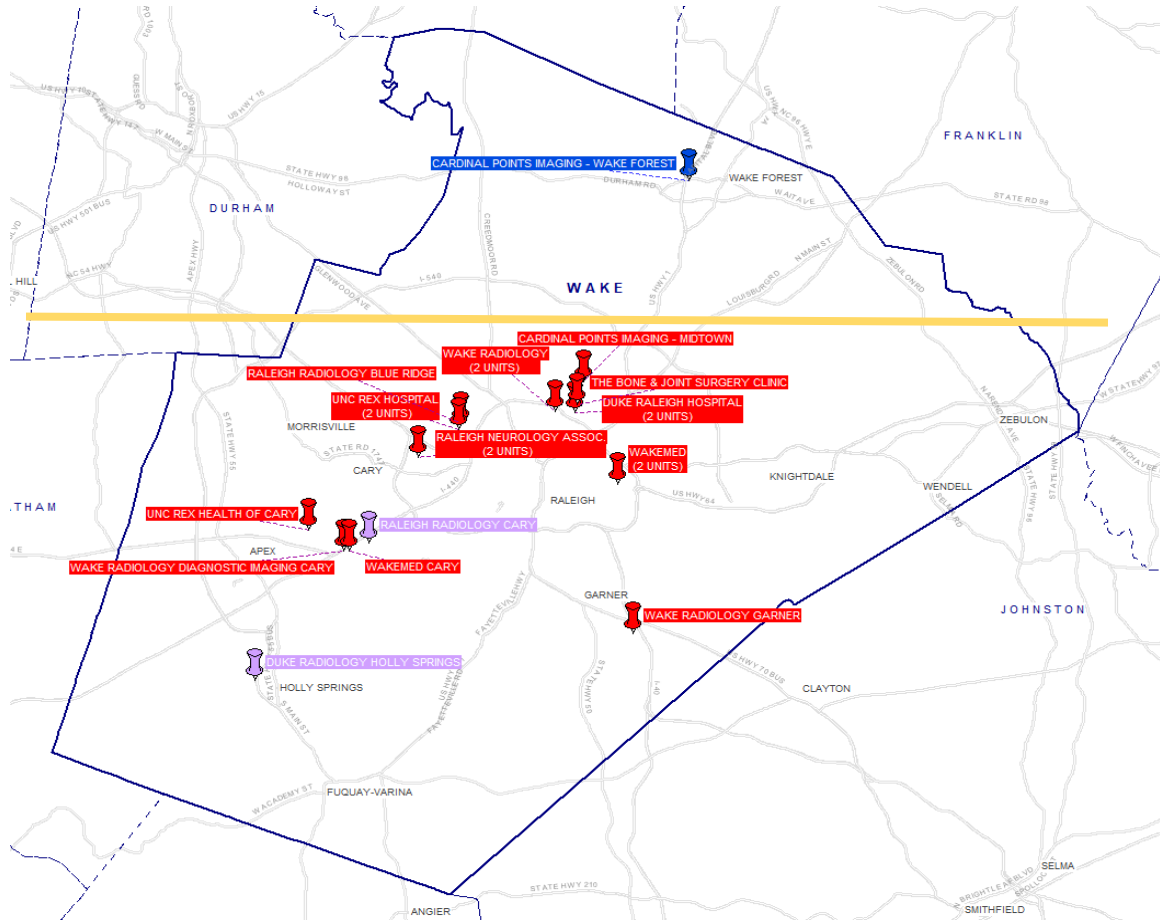
Wake County Fixed MRI Scanners by Geographic Location

Municipality	2019 Population	# Of Existing & Approved Fixed MRI Scanners	Population/Scanner
Raleigh	470,396	13	36,184
Cary/Morrisville	191,088	3	63,696
Apex/Holly Springs/Fuquay-Varina	125,706	2	62,853
Wake Forest/Rolesville	44,390	0	--
Garner	32,213	1	32,213
Knightdale/Wendell/Zebulon	29,944	0	--
Wake County	1,085,297	19	57,121

Source: NC OSBM Municipal Population Estimates (2019 population is the most recent data available), 2021 SMFP

The current distribution of Wake County fixed MRI scanners is heavily concentrated in Raleigh (13 scanners), with western and southern Wake County hosting all of the remaining six fixed scanners. As shown in the following map, northern Wake County does not have any fixed MRI scanners.

Location of Wake County Fixed MRI Scanners (Including proposed CPIC Wake Forest)



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

- **Access for the Medically Underserved.** Each applicant projects Medicare and Medicaid access based on their historical experience. All are effective alternatives as to access for Medicare and Medicaid patients; however, the DUHS and Wake Radiology applications both fail to conform to multiple review criteria and to the MRI administrative rules and neither application is approvable.

PHSNC projects the highest charity care dollars per MRI procedure, as well as the greatest access by charity care as a percentage of net revenues, as summarized in the following table. Therefore, PHSNC is the most effective alternative with regard to provision of charity care.

Projected Charity Care

Year 3	PHSNC	DUHS	Wake Radiology
Charity Care \$/MRI Procedure	\$26.39	\$18.49	\$4.17
Charity Care % of Net Revenue	5.22%	3.53%	0.45%

Source: CON Applications, Section Q, Form F.2b.

- **Projected Average Revenue per MRI Procedure.** As a value-based imaging provider, PHSNC proposes market-competitive charges for the fixed MRI scanner in Wake Forest, projecting the lowest average net revenue per MRI procedure of the three competing applicants. Therefore, the PHSNC application is the most effective alternative.

Projected Average Net Revenue/MRI Procedure

	PHSNC	DUHS	Wake Radiology
Average Net Revenue, Year 3	\$505	\$523	\$925

Source: CON Applications, Section Q, Form F.2b.

- **Projected Average Operating Expense per MRI Procedure.** PHSNC proposes market-competitive operating expenses for its fixed MRI scanner in Wake Forest, projecting the lowest average operating expense per MRI procedure of the three competing applicants. Therefore, the PHSNC application is the more effective alternative.

Projected Average Operating Expense/MRI Procedure

	PHSNC	DUHS	Wake Radiology
Average Operating Expense, Year 3	\$347	\$382	\$647

Source: CON Applications, Section Q, Form F.3b.

Specific comments regarding the Duke Imaging North Raleigh application (J-12073-21)

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 does not adequately demonstrate the need for the proposed project based on reasonable utilization projections, did not propose the least costly or most effective alternative, and did not show that its proposal is not unnecessarily duplicative of existing MRI resources. Therefore, DUHS fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2021 SMFP. The discussions regarding analysis of need, including projected utilization, found in Criterion (3), alternative methods in Criterion (4), unnecessary duplication in Criterion (6), and the applicable .2700 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the DUHS application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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.”*

DUHS failed to identify the population to be served by the proposed project. Specifically, on page 28 of its application, DUHS provides a table projecting patient origin by county for the initial three project years. As shown in the table, reproduced below, the projected patient origin for all three years actually totals 101% (not 100% as shown on the table), which is not possible. Therefore, DUHS did not adequately identify the population to be served.

MRI	Duke Imaging North Raleigh					
	1 st Full FY		2 nd Full FY		3 rd Full FY	
	07/01/2023 to 06/30/2024		07/01/2024 to 06/30/2025		07/01/2025 to 06/30/2026	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Wake	2843	66%	2878	66%	2913	66%
Franklin	201	5%	203	5%	205	5%
Johnston	198	5%	200	5%	203	5%
Cumberland	93	2%	94	2%	95	2%
Nash	77	2%	78	2%	78	2%
Harnett	74	2%	75	2%	76	2%
Wayne	51	1%	52	1%	52	1%
Other	787	18%	796	18%	806	18%
Total	4323	100%	4375	100%	4428	100%

^Other Includes obstetrics patients originating from Harnett and Johnston counties.

* This should match the name provided in Section A, Question 4.

** Home health agencies should report the number of unduplicated clients.

DUHS operates two fixed MRI scanners at Duke Raleigh Hospital (DRAH) and a third fixed MRI scanner in Holly Springs. The Holly Springs fixed MRI scanner, which DUHS just made operational in 2020, will absorb a substantial portion of the DUHS hospital-based MRI volume, as DUHS projects in its application. DUHS thus now has a recently approved, owned and operational lower cost freestanding diagnostic imaging option in Wake County for its patients who are appropriate for a freestanding setting. With that scanner not yet one year into operation, DUHS cannot yet demonstrate need for yet another fixed MRI scanner in Wake County.

The DUHS application limits access to the proposed MRI (as well as the new Holly Springs scanner) 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 Imaging North Raleigh to serve its own DUHS patients. For example, the few physician letter of support provided in Exhibit C.4 of the DUHS application were written by DUHS-affiliated physicians. DUHS failed to document any local community support or local physician support from those areas for its project. 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 discussed below, 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.

The DUHS application proposal does not adequately demonstrate the need that its identified population has for the services proposed. As stated on page 94 of its application, Step 3 of the DUHS methodology for projecting utilization of the proposed North Raleigh scanner projects a 40% shift of DRAH outpatient MRI volume to the freestanding scanner. As DUHS itself states in the application, “40% is a very conservative assumption of the percentage of patients who may prefer the cost structure of an IDTF.” Indeed, given the high charge structure for an MRI procedure at DRAH, it is likely that a much higher percentage of DUHS MRI patients would shift to the IDTF scanner. The DRAH scanners are likely to be underutilized, with excess capacity.

In addition, to produce the volume necessary to meet the MRI performance standards, DUHS relies on an unsupported and unjustified projection methodology to project utilization of the Holly Springs scanner. Projected MRI utilization in DUHS' primary service area (consisting of Apex and Southwest Wake County, plus Chatham and Harnett County zip codes) and DUHS' secondary service area (consisting of the remaining Wake County area zip codes) is not clearly explained in the application. The DUHS application identifies that an estimated 1,258 MRI scans will shift from existing DUHS MRI scanners to the Holly Springs magnet (see page 98.) To this unclear calculation, DUHS projects another incremental increase of 2,526 MRI procedures in 2026 based on “an increase in share of total volume in the proximate zip codes”. 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 that the DUHS application failed to document local physician and community support in its proposed primary service area. The DUHS application does not document the basis for projecting this capture of additional market share. 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.

The DUHS application relies on convenience, not need, to support its projected shift volume to the Holly Springs location from various other DUHS locations, despite other existing or approved DUHS MRI locations being viable as convenient alternative locations. The DUHS application appears to be designed more to preserve DUHS market share of existing MRI procedures and prevent other market entry than to serve an underserved population. Thus, the application fails to demonstrate the need of the population to be served.

In summary, DUHS failed to demonstrate that the projected procedure volume for all of its existing and proposed fixed MRI scanners is based on reasonable and supported assumptions. Therefore, the DUHS application is nonconforming to 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.”*

DUHS does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria and administrative rules. An application that cannot be approved cannot be the most effective alternative. Also, the DUHS proposal is not the most effective or least costly option for several other reasons, including:

- DUHS’s capital cost of \$4.945M is by far the highest of all the applications.
- DUHS is proposing a new diagnostic center with a single modality; MRI. This is a much more expensive alternative than adding MRI services to an existing facility.
- DUHS did not describe exploration of the alternative of shifting one of the existing hospital-based fixed MRI scanners to the freestanding IDTF setting, given that, as it states in its own application, a large percentage of DUHS patients would prefer the cost structure of an IDTF.

Therefore, the DUHS application is not conforming to 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.”*

DUHS’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable, and therefore the application is not conforming to 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 its proposal would not result in unnecessary duplication of fixed MRI service because DUHS just recently made operational an additional Wake County fixed MRI scanner in Holly Springs. Therefore, DUHS is proposing the unnecessary duplication of a fixed MRI scanner that DUHS has developed within the past year. In addition, the utilization projections are unreasonable. Therefore the application is not conforming to Criterion (6).

Criteria (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.”*

DUHS’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions. And DUHS is proposing to unnecessarily duplicate a fixed MRI scanner that it just recently made operational. The discussion regarding projected utilization, alternatives, and unnecessary duplication are found in Criteria (3), (4), (5), and (6), are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

On page 45 of its application, DUHS acknowledges that it owns and operates a fixed MRI scanner at Holly Springs which began service on June 16, 2020. DUHS then appears to intimate that because the scanner has not been in operation for 12 months that the rule is not applicable. However, the rule is applicable because 1) the applicant, DUHS, is proposing “to acquire a fixed MRI scanner”, and 2) DUHS owns fixed MRI scanners in Wake County. Therefore, DUHS meets all the criteria for this Rule to apply.

DUHS did not provide data for the Holly Springs fixed MRI scanner. With the CON application filing date of April 15, 2021, DUHS has approximately 10 months of data available regarding utilization of the Holly Springs scanner. Because DUHS failed to provide the necessary information, DUHS did not demonstrate that the fixed MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures for the most recent 12 month period for which DUHS has such historical data. Therefore, the DUHS application is non-conforming to this Rule.

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

The DUHS application does not conform to the .2703(b)(3,4 & 6) performance standards applicable for the review of fixed MRI scanners. Utilization projections for the proposed DUHS fixed MRI scanner are not based on reasonable assumptions and methodology. The discussions regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Specific comments regarding the Wake Radiology Garner application (J-12068-21)

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.*

Wake Radiology does not demonstrate the need for the proposed project based on reasonable utilization projections, and also does not demonstrate that the proposed project does not represent unnecessary duplication of existing MRI capacity at Wake Radiology and UNC Rex. Therefore, Wake Radiology fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2021 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3), unnecessary duplication found in Criterion (6), and the applicable .2700 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Wake Radiology application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

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.”*

Wake Radiology’s projections of MRI procedures are unreasonable and unrealistic. Utilization projections for the existing Wake Radiology fixed and mobile MRI scanners are not based on reasonable assumptions and methodology. And in fact, as described later in these comments, Wake Radiology tries to cover this up by claiming on page 64 of its application that the MRI Performance Standards do not apply to its MRI application. This of course, is erroneous, as will be described.

In Exhibit C.12-1 of its application, Wake Radiology provides a confusing narrative of the fixed MRI scanner that will be located at UNC Rex Holly Springs Hospital. As stated in Exhibit C.7-1, the fixed MRI scanner that will be developed at UNC Rex Holly Springs Hospital was taken out of service from Cary in December 2018, pending its redeployment at UNC Rex Holly Springs Hospital. Thus, the applicant has not used this existing MRI scanner capacity for approximately two and one half years and counting. Also in Exhibit C.7-1, Wake Radiology states its belief that it will prevail in its litigation of denial of its 2019 CON application to develop a fixed MRI scanner in Cary. Thus, Wake Radiology is proposing, with this 2021 fixed MRI scanner CON application, that it will nearly double its

existing operational fixed MRI scanner capacity (two fixed scanners at Wake Radiology and two fixed scanners at UNC Rex, to be supplemented by the Holly Springs Hospital fixed MRI scanner, the previously proposed Cary fixed MRI scanner, and the newly proposed Garner fixed MRI scanner. The following table from Wake Radiology’s Exhibit C.7-1 summarizes this overly optimistic projected fixed MRI scanner inventory and utilization. Of note, this does not even include the two mobile MRI scanners already owned and operated by WR Imaging within Wake County.

Projected Total Weighted Scans

	<i>PY3</i>	<i>Fixed Magnet</i>	<i>Total Average</i>
Wake Radiology Garner	5,251	1	
Wake Radiology Cary	6,194	1	
Wake Radiology Raleigh	12,675	2	
UNC REX Hospital	10,042	2	
UNC REX Holly Springs Hospital	1,455	1	
Total	35,617	7	5,088

This projected utilization total is fairly incredible. Wake Radiology is projecting to perform 35,617 weighted MRI scans on seven fixed MRI scanners in CY2025, as compared to its actual combined CY2020 fixed MRI scanner utilization of 24,811 weighted MRI scans for the two UNC Rex fixed scanners, the two Wake Radiology Raleigh fixed MRI scanners, and the Alliance fixed scanner at Wake Radiology Cary. This represents a 43.6% projected volume increase over the projected five-year period. This is simply not realistic.

In Exhibit C.7-3 of its application, Wake Radiology summarizes its historical utilization of its two existing mobile MRI scanners. This data shows that the utilization of neither existing WR Imaging mobile scanner met the required performance standard (.2703(b)(2)) of 3,328 weighted scans for the most recent 12-month period, with just 3,194 and 2,358 weighted scans, respectively, during CY2020.

Regarding projected mobile MRI scanner utilization, Wake Radiology states that one of its two existing mobile MRI scanners will serve a new Panther Creek location. This is not a proven site for provision of MRI services, and has no historical utilization. Yet in its application, Wake Radiology projects that this mobile scanner will increase its current utilization by an astounding average annual rate of growth of 7.3%. This is neither realistic nor reasonable. Wake Radiology chose to use this high growth rate because it is necessary to manufacture enough projected volume in order to exceed the .2703 mobile MRI performance standard of 3,328 weighted scans. In addition, Wake Radiology claims that its other existing mobile MRI scanner will continue to serve the Wake Radiology Cary location in addition to the fixed MRI service that Wake Radiology projects to serve at the same Cary

site. This is neither realistic nor reasonable. In fact, as shown in the following excerpt from table 17E-1 of the Proposed 2022 SMFP, for FFY2019 Wake Radiology reported providing zero MRI scans at the Wake Radiology Cary location.

DRAFT - 05/05/2021

Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outpt No Contrast	Outpt Contrast	Inpt No Contrast	Inpt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Wake	Mobile	J-007008-04	Raleigh Neurosurgical Clinic (Foundations Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Neurosurgical Clinic (Foundations Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Orthopaedic Clinic (Alliance HealthCare Services)	0	0.01	30	30	0	0	0	30			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.06	286	286	0	0	0	286			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.07	313	313	0	0	0	313			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.45	2,174	2,174	0	0	0	2,174			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.21	989	989	0	0	0	989			
Wake	Mobile	Grandfathered	Raleigh Orthopedic (Alliance Healthcare Services)	0	0.16	745	743	2	0	0	746			
Wake	Mobile	Grandfathered	Raleigh Orthopedic (Alliance Healthcare Services)	0	0.01	64	64	0	0	0	64			
Wake	Mobile	Grandfathered	Raleigh Radiology (Alliance HealthCare Services)	0	0.09	453	357	96	0	0	491			
Wake	Mobile	Grandfathered	Raleigh Radiology - Brier Creek (Foundations Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Radiology -esity Varma (Alliance Healthcare Services)	0	0.29	1,377	1,010	367	0	0	1,524			
Wake	Mobile	J-007012-04	Wake Radiology Cary (Wake Radiology)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	J-007012-04	Wake Radiology -esity Varma (Wake Radiology)	0	0.08	393	256	137	0	0	448			
Wake	Mobile	J-011291-17	Wake Radiology Rex Holly Springs (Wake Radiology)	0	0.06	298	298	0	0	0	298			

Please also see the discussion of these projections in the following response regarding the .2700 MRI Administrative Rules. In summary, Wake Radiology failed to demonstrate that its projected fixed MRI scanner utilization is based on reasonable and supported assumptions. Therefore, the Wake Radiology application is nonconforming to 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.”

Wake Radiology does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need, because the application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be the most effective alternative. Therefore, the Wake Radiology application is not conforming to 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.”*

Wake Radiology’s financial projections are not based on reasonable utilization projections, as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable, and the Wake Radiology application is not conforming to 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.”*

Wake Radiology fails to demonstrate that its proposal would not result in unnecessary duplication of existing MRI services. As described in response to the MRI Administrative Rules below, Wake Radiology did not demonstrate adequate historical utilization of its two existing mobile MRI scanners. Therefore, Wake Radiology did not demonstrate that its proposal to acquire an additional fixed MRI scanner will not result in unnecessary duplication of its own existing MRI health service capabilities. Also, Wake Radiology did not demonstrate that the proposed fixed MRI scanner is needed in addition to the abundant existing fixed MRI capacity owned and operated by WR Imaging and by related entity UNC Rex (some of which is not even currently in use). WR Imaging is a joint venture of Wake Radiology and UNC Rex, which combined currently own and operate five fixed MRI scanners in Wake County. The Wake Radiology application appears to be designed to preserve Wake Radiology/UNC Rex market share of existing MRI procedures, and to prevent other market entry, and thus represents unnecessary duplication of existing MRI capacity at Wake Radiology and UNC Rex. Therefore the application is not conforming to Criterion (6).

Criteria (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.”*

Wake Radiology’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost effective services. The discussion regarding projected alternatives, financial projections, and unnecessary duplication found in Criteria (4), (5), and (6) are incorporated herein by reference.

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:

(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;

On page 64 of its application, Wake Radiology claims that this rule is not applicable due to the COVID-19 pandemic. However, prior to the pandemic, Wake Radiology made a similar claim (different excuse) that .2703(b)(1) was not applicable in its 2019 CON application to develop a fixed MRI scanner in Wake County. On pages 106-107 of the Agency Findings for the 2019 Wake County MRI Review, the Agency explained how Wake Radiology was incorrect in claiming the rule was not applicable. The same explanation applies in this 2021 Wake County MRI Review. The Rule applies because 1) the applicant, WR Imaging, is proposing “to acquire a fixed MRI scanner”, and 2) WR Imaging owns two fixed MRI scanners in Wake County. Therefore, WR Imaging meets all the criteria for this Rule to apply.

Wake Radiology did not provide data for the two WR Imaging fixed MRI scanners for the most recent 12-month period for which the applicant has data. Furthermore, WR Imaging does not demonstrate that it does not have access to or does not know the historical data for a 12-month period for the two fixed MRI scanners it owns. Thus, WR Imaging did not demonstrate that the two fixed MRI scanners it owns in Wake County performed an average of 3,328 weighted MRI procedures for the most recent 12 month period for which WR Imaging has such historical data, nor did WR Imaging demonstrate that it could not provide historical data for the two fixed MRI scanners it owns in Wake County for a 12 month period. Therefore, the Wake Radiology application is non-conforming to this Rule.

(2) 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 [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];

On page 64 of its application, Wake Radiology claims that this rule is not applicable due to the COVID-19 pandemic. However, prior to the pandemic, Wake Radiology made a similar claim (different excuse) that .2703(b)(2) was not applicable in its 2019 CON application to develop a fixed MRI scanner in Wake County. On pages 108-109 of the

Agency Findings for the 2019 Wake County MRI Review, the Agency explained how Wake Radiology was incorrect in claiming the rule was not applicable. The same explanation applies in this 2021 Wake County MRI Review. The Rule applies because 1) the applicant, WR Imaging, is proposing “to acquire a fixed MRI scanner”, and 2) WR Imaging owns two mobile MRI scanners in Wake County. Therefore, WR Imaging meets all the criteria for this Rule to apply.

Although on pages 64-65 of its application Wake Radiology obfuscates by choosing not to provide any historical information in response to the .2703(b)(2) administrative rule, in Exhibit C.7-3 of its application Wake Radiology provides historical utilization for its two mobile MRI scanners, showing that each mobile scanner performed below the required 3,328 weighted MRI procedures. The historical utilization tables from the Wake Radiology exhibit book are presented below for the Project Analyst’s ease of reference.

These sites have historically experienced the following level of combined MRI utilization:

WR Imaging Mobile #1 MRI Historical Utilization

	CY16	CY17	CY18	CY19	CY20*	CAGR^
Outpatient No Contrast	1,564	1,533	1,795	1,627	1,773	3.2%
Outpatient With Contrast	382	416	420	811	1,015	27.7%
Total Scans	1,946	1,949	2,215	2,438	2,788	9.4%
Total Weighted Scans**	2,099	2,115	2,383	2,762	3,194	11.1%
Weighted Scans Annual Growth	NA	0.8%	12.7%	15.9%	15.6%	

*CY 2020 normalized to adjust for the months of March, April, and May when utilization was temporarily impacted by the COVID 19 pandemic.

^Compound annual growth rate.

**Weighted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

Source: Wake Radiology internal data.

WR Imaging Mobile #2 MRI Historical Utilization

	CY16	CY17	CY18	CY19	CY20*	CAGR
Outpatient No Contrast	406	355	481	966	1,207	31.3%
Outpatient With Contrast	476	579	944	760	822	14.7%
Total Scans	882	934	1,425	1,722	2,029	23.2%
Total Weighted Scans**	1,072	1,166	1,803	2,026	2,358	21.8%
Weighted Scans Annual Growth	NA	8.7%	54.6%	12.4%	16.4%	

*CY 2020 normalized to adjust for the months of March, April, and May when utilization was temporarily impacted by the COVID 19 pandemic.

**Weighted scans based on 1.0 weight for outpatient no contrast and 1.4 weight for outpatient with contrast.

Source: Wake Radiology internal data.

Therefore, the Wake Radiology application is non-conforming to this Rule, and its MRI application is not approvable.

(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:

(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,

(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,

(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,

(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or

(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;

(5) demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and

(6) document the assumptions and provide data supporting the methodology used for each projection required in this Rule.

The Wake Radiology application does not conform to each of these performance standards applicable for the review of fixed MRI scanners. Utilization projections for the existing Wake Radiology fixed and mobile MRI scanners are not based on reasonable assumptions and methodology. And in fact, as previously described, Wake Radiology tries to cover this up by claiming on page 64 of its application that the MRI Performance Standards do not apply to its application. This of course, is erroneous, as previously described.

In Exhibit C.12-1 of its application, Wake Radiology provides a confusing narrative of the fixed MRI scanner that will be located at UNC Rex Holly Springs Hospital. As stated in Exhibit C.7-1, the fixed MRI unit that will be developed at UNC Rex Holly Springs Hospital was taken out of service from Cary in December 2018, pending its redeployment at UNC Rex Holly Springs Hospital. Thus, this MRI scanner capacity has not been used (thus far) for approximately two and one half years. Also in Exhibit C.7-1, Wake Radiology states its belief that it will prevail in its litigation of denial of its 2019 CON application to develop a fixed MRI scanner in Cary. Thus, Wake Radiology is proposing, with this 2021 fixed MRI scanner CON application, that it will nearly double its existing operational fixed MRI scanner capacity (two fixed scanners at Wake Radiology and two fixed scanners at UNC Rex, to be supplemented by the planned Holly Springs fixed MRI scanner, the previously proposed Cary fixed MRI scanner, and the newly proposed Garner fixed MRI scanner. The following table from Wake Radiology’s Exhibit C.7-1 summarizes this projected fixed MRI scanner inventory and utilization.

Projected Total Weighted Scans

	<i>PY3</i>	<i>Fixed Magnet</i>	<i>Total Average</i>
Wake Radiology Garner	5,251	1	
Wake Radiology Cary	6,194	1	
Wake Radiology Raleigh	12,675	2	
UNC REX Hospital	10,042	2	
UNC REX Holly Springs Hospital	1,455	1	
Total	35,617	7	5,088

This projected utilization total is fairly incredible. Wake Radiology is projecting to perform 35,617 weighted MRI scans on seven fixed MRI scanners in CY2025, as compared to its actual combined CY2020 fixed MRI scanner utilization of 24,811 weighted MRI scans for the two UNC Rex fixed scanners, the two Wake Radiology Raleigh fixed MRI scanners, and the Alliance fixed scanner at Wake Radiology Cary. This represents a 43.6% projected volume increase over the projected five-year period. This is simply not realistic.

In Exhibit C.7-3 of its application, Wake Radiology summarizes its historical utilization of the two existing mobile MRI scanners. This data shows that the utilization of neither existing WR Imaging mobile scanner met the required performance standard (.2703(b)(2)) of 3,328 weighted scans for the most recent 12-month period, with just 3,194 and 2,358 weighted scans, respectively, during CY2020.

Regarding projected mobile MRI scanner utilization, Wake Radiology states that one of its two existing mobile MRI scanners will serve a new Panther Creek location. This is not a proven site for provision of MRI services, and has no historical utilization. Yet in its application, Wake Radiology projects that this mobile scanner will increase its current utilization by an astounding average annual rate of growth of 7.3%. This is neither realistic nor reasonable. This high growth rate is necessary for Wake Radiology to manufacture enough projected volume in order to exceed the .2703 mobile MRI performance standard of 3,328 weighted scans. In addition, Wake Radiology claims that its other existing mobile MRI scanner will continue to serve the Wake Radiology Cary location in addition to the fixed MRI services that Wake Radiology projects to serve at the same Cary site. This is neither realistic nor reasonable. In fact, as shown in the following excerpt from table 17E-1 of the Proposed 2022 SMFP, for FFY2019 Wake Radiology reported providing zero MRI scans at the Wake Radiology Cary location.

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Table 17E-1: MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents

A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
Service Area	Service Type	CON #	Service Site (Provider/Owner)	Fixed Magnet	Fixed Equiv	Total MRI Scans	Outpt No Contrast	Outpt Contrast	Inpt No Contrast	Inpt Contrast	Adjusted Total	Area Avg Procs	Threshold	MRI Need
Wake	Mobile	J-007008-04	Raleigh Neurosurgical Clinic (Foundation Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Neurosurgical Clinic (Foundations Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Orthopaedic Clinic (Alliance HealthCare Services)	0	0.01	30	30	0	0	0	30			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.06	286	286	0	0	0	286			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.07	313	313	0	0	0	313			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.45	2,174	2,174	0	0	0	2,174			
Wake	Mobile	J-007756-06	Raleigh Orthopaedic Clinic (Raleigh Orthopaedic Clinic, PA)	0	0.21	989	989	0	0	0	989			
Wake	Mobile	Grandfathered	Raleigh Orthopedic (Alliance Healthcare Services)	0	0.16	745	743	2	0	0	746			
Wake	Mobile	Grandfathered	Raleigh Orthopedic (Alliance Healthcare Services)	0	0.01	64	64	0	0	0	64			
Wake	Mobile	Grandfathered	Raleigh Radiology (Alliance HealthCare Services)	0	0.09	453	357	96	0	0	491			
Wake	Mobile	Grandfathered	Raleigh Radiology - Brier Creek (Foundations Health Mobile Imaging, LLC)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	Grandfathered	Raleigh Radiology - Pigeon Forge (Alliance Healthcare Services)	0	0.29	1,377	1,010	367	0	0	1,524			
Wake	Mobile	J-007012-04	Wake Radiology Cary (Wake Radiology)	0	0.00	0	0	0	0	0	0			
Wake	Mobile	J-007012-04	Wake Radiology Cary (Wake Radiology)	0	0.08	393	256	137	0	0	448			
Wake	Mobile	J-011291-17	Wake Radiology Rex Holly Springs (Wake Radiology)	0	0.06	298	298	0	0	0	298			

In summary, Wake Radiology did not meet the performance standards in .2703(b)(1) and (2), and the application is therefore non-conforming. Also, the fixed and mobile MRI utilization projections are clearly not reasonable, and the application is not conforming to .2703(b)(3), (4), (5) and (6).