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August 2, 2010

Mr. Greg Yakaboski, Project Analyst  
Mr. Craig Smith, Section Chief  
Certificate of Need Section  
Division of Facility Services  
NC Department of Health and Human Services  
701 Barbour Drive  
Raleigh, North Carolina 27626

RE: Comments on Wake County MRI Certificate of Need Application filed by Wake Radiology Diagnostic Imaging, Inc. and Wake Radiology Services, LLC – Project ID# **J-8534-10**

Dear Mr. Yakaboski and Mr. Smith:

On behalf of Pinnacle Health Services, LLC, thank you for the opportunity to comment on the above-referenced application for a Certificate of Need. We trust that you will take these comments into consideration during your review.

The Findings of Fact for the Certificate of Need Statute (GS 131E-175), the legislature identified several guiding principles aimed at strengthening the health care delivery system in North Carolina and insuring its population of broad access to services. Among these, numbers three, four, and six bear special consideration in this review.

- (3) That, if left to the market place to allocate health service facilities and health care services, geographical misedistribution of these facilities and services would occur and, further, less than equal access to all population groups, especially those that have traditionally been medically underserved, would result.
- (4) That the proliferation of unnecessary health service facilities results in costly duplication and underuse of facilities, with the availability of excess capacity leading to unnecessary use of expensive resources and overutilization of health care services.
- (6) That excess capacity of health service facilities places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.

We believe that the application submitted by Wake Radiology has serious shortcomings and fails to meet the aforementioned guiding principles. The following paragraphs demonstrate specific areas where we believe the application is unclear, or fails to comply with the statutory review criteria or administrative rules.

**Wake Radiology Diagnostic Imaging, Inc.  
and Wake Radiology Services, LLC  
Project ID# J-8534-10**

**NONCOMPLIANCE WITH CON REVIEW CRITERIA**

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, ambulatory surgery operating rooms, or home health offices that may be approved.*

Wake Radiology's proposed application is not consistent with applicable policies in the State Medical Facilities Plan (SMFP). The application does not demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value. Therefore, Wake Radiology fails to be consistent with Policy GEN-3: BASIC PRINCIPLES and is thus non-conforming to Review Criterion (1).

Additionally, the proposed project is not consistent with all the special rules in 10A NCAC 14C Section .2700 – Criteria and Standards for Magnetic Resonance Imaging Scanners, and is thus not conforming to Review Criterion (1).

The discussion below outlines how the applicant is inconsistent with Policy GEN-3.

Safety and Quality

Safety and quality can not be assumed because the applicant fails to adequately demonstrate that the proposed project is the most effective alternative or that the proposed project has the availability of health manpower. Please see discussion in Review Criterion (4) and (7).

Access

Wake Radiology's proposed payor mix includes an unreasonably low percentage of Medicaid and Self Pay beneficiaries. Therefore, access to services for these individuals is not documented. Please see Review Criterion (3) and (13c).

Value

It is not possible to determine that the proposed project will maximize healthcare value, because the applicant does not adequately demonstrate that the population to be served has a need for the services proposed. Please see discussion in Review Criterion (3). It is not possible to determine that the proposed project will maximize healthcare value, because the applicant does not adequately demonstrate that the most effective alternative has been proposed. Please see discussion in Review Criterion (4). It is not possible to determine that the proposed project

will maximize healthcare value, because the applicant does not adequately demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative. Please see discussion in Review Criterion (12).

For these reasons, Wake Radiology failed to demonstrate that its application is consistent with the applicable policies of the SMFP.

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.*

**Projected Utilization**

Wake Radiology is proposing to own and operate a fixed MRI at its Garner office. Additionally, Wake Radiology will continue to own and operate two fixed MRIs at its Raleigh MRI Center and one mobile MRI that serves four host sites in Raleigh, Cary, Garner, and Northwest (Raleigh). As such, in its CON application, Wake Radiology is required to provide utilization projections for all four MRIs.

**Proposed Fixed MRI**

Wake Radiology projects the future utilization for its fixed MRI to be located in its Garner Office using historical utilization data for its Garner Office. That office is served by its mobile scanner 40 hours per week. According to its application, the Wake Radiology Garner Office performed 2,323 MRI procedures and had a 3.2 percent market share of all the Wake County MRI procedures in FY 2009. Wake Radiology projects that the Garner Office will perform 4,392 MRI procedures and have a 5.0 percent market share of all the Wake County MRI procedures in FY 2014, on its proposed fixed MRI. Please see the table below.

**Garner Office MRI Utilization**

	Historical			Projected				
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Garner Office MRI Scans	2,263	2,762	2,323	2,398	2,495	3,246	3,799	4,392
Total Wake County MRI Scans	65,582	65,892	72,036	74,951	77,984	81,140	84,423	87,840
Market Share	3.5%	4.2%	3.2%	3.2%	3.2%	4.0%	4.5%	5.0%

These projections are unreasonable for several reasons. Wake Radiology provides no quantitative justification for its increase in market share. Wake Radiology states that it proposes to increase market share based on:

1. Physician referral estimates.
2. The first fixed MRI in Garner.
3. Increased hours of availability.
4. Freestanding charge structure.

These qualitative explanations do not justify an increase of 2,069 procedures (90 percent) and an increase of 66 percent increase in market share. Wake Radiology provides no information about the source of new market share or the impact of the change in market share on other existing providers. This is important because of the size of the Garner population.

Additionally, Wake Radiology examined only one year of historical MRI utilization for its Garner Office. Had it examined two years of historical data, it would have showed that its MRI utilization decreased by 439 procedures (16 percent) and its market share dropped by 24 percent. Wake Radiology provides no explanation for this drop. Three years of historical data, would have showed that its MRI utilization increased by only 60 procedures (2 percent) during that time period and that its market share actually decreased by 9 percent.

The table below shows revised MRI utilization projections for the Garner Office with the market share generously kept constant. This would have been more reasonable. As demonstrated in the table, the Garner office would not meet the performance standard in the third year of the project, FY 2014.

**Revised Garner Office MRI Utilization  
Constant Market Share**

	Historical			Projected				
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Garner Office MRI Procedures	2,263	2,762	2,323	2,398	2,495	2,596	2,702	2,811
Total Wake County MRI Procedures	65,582	65,892	72,036	74,951	77,984	81,140	84,423	87,840
Market Share	3.5%	4.2%	3.2%	3.2%	3.2%	3.2%	3.2%	3.2%

A linear projection of historical MRI utilization produces even fewer MRI procedures. Again, the Garner office would not meet the performance standard in the third year of the project, FY 2014.

**Revised Garner Office MRI Utilization  
Linear Projection**

	Historical			Projected				
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Garner Office MRI Procedures	2,263	2,762	2,323	2,509	2,539	2,569	2,599	2,629

Forecast for Existing Fixed WR MRIs

Forecasts for Wake Radiology's existing fixed MRIs are overly optimistic. Wake Radiology projects future utilization for two existing fixed MRIs at its Raleigh MRI Center based on its own historical utilization and population growth. Wake Radiology "applied three fourths (75 percent) of the projected population growth of Wake County (2.9 percent \* 75 percent = 2.2 percent) to its most recent year's utilization (FY 2009)." Please see the table below.

**Existing Fixed MRI Utilization**

	Historical			Projected				
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Raleigh MRI Procedures	11,308	11,272	10,078	10,297	10,519	10,747	10,979	11,216

This is not reasonable. Over the last three years, while the population of Wake County has been increasing, utilization of Wake Radiology's two fixed MRIs has been decreasing. Please see the table below.

**Existing Fixed MRI Utilization  
and Wake County Population**

	FY 2007	FY 2008	FY 2009
MRI Procedures	11,308	11,272	10,078
<b>Percent Change</b>		<b>-0.3%</b>	<b>-10.6%</b>
Wake County Population	831,537	866,438	892,607
<b>Percent Change</b>		<b>4.2%</b>	<b>3.0%</b>

Sources: 2009-2011 SMFP – Historical MRI Utilization

<http://www.osbm.state.nc.us> – Wake County Population

Wake Radiology provided no assumption, explanation, or documentation regarding why its fixed MRI utilization will change this pattern and increase as the Wake County population increases. No supporting information in the application justifies the projected reversal

In fact, a linear projection of fixed MRI utilization based on Wake Radiology's recent three-year history shows that its two fixed MRI scanners would not meet the required performance standard by the third year of the project, FY 2014. Please see the table below.

**Revised Existing Fixed MRI Utilization  
Linear Projection**

	Historical			Projected				
	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014
Fixed MRI Procedures	11,308	11,272	10,078	9,656	9,041	8,426	7,811	7,196

Existing Mobile MRI

Wake Radiology's mobile MRI has historically served four host sites, Raleigh, Cary, Garner, and Northwest (Raleigh). According to its CON application, Wake Radiology will change the host sites to Raleigh, Northwest (Raleigh), and Wake Forest. Thus it will eliminate mobile MRI services in both Cary and Garner. Wake Radiology projects mobile MRI volume for each proposed host site.

- Wake Radiology projects mobile MRI utilization at its Raleigh site based on a percentage of its proposed existing fixed MRI utilization at its Raleigh site. Please see the discussion above as to why Wake Radiology's projections for its existing fixed MRI utilization is not reasonable.
- Wake Radiology projects mobile MRI utilization at its Northwest site based on its historical utilization and proposed schedule. On page 51 of its application, Wake Radiology states that it "began offering mobile MRI services at Northwest in September 2009, and currently offers services one day per week. Upon implementation of the fixed MRI in Garner, Wake Radiology will increase access to two days each week. Based on current utilization and discussions with the Northwest site MRI manager, Wake Radiology projects the following mobile MRI scans at the Northwest location."

**Wake Radiology Northwest  
Mobile MRI Utilization**

	FY 2012	FY 2013	FY 2014
MRI Scans	815	932	1,048

This is not reasonable. Wake Radiology does not provide any historical MRI utilization at its Northwest site. Therefore, it is impossible to determine if its projections that are based on history are reasonable. According to the proposed 2011 SMFP, the Northwest site performed 22 MRI scans in fiscal year 2009. If the MRI began operating in September of 2009, then it operated one month of fiscal year 2009. This translates to 264 annualized MRI scans ( $22 * 12 = 264$ ). If Wake Radiology doubles its access and increases from one to two days per week, this would translate to 528 annualized scans ( $264 * 2 = 528$ ). Therefore, historical utilization does not justify these projections. Additionally, it is not reasonable to base MRI utilization on “discussions with the Northwest site MRI manager.”

- Wake Radiology projects mobile MRI utilization at its Wake Forest office based on its historical utilization and proposed schedule. On pages 52 and 53 of its application, Wake Radiology states that it “began offering mobile MRI services at its Wake Forest office through Alliance in the fall of 2009. Based on current utilization and discussions with the Wake Forest site MRI Manager, Wake Radiology projects the following mobile MRI scans at the Wake Forest location.”

**Wake Radiology Wake Forest  
Mobile MRI Utilization**

	<b>FY 2012</b>	<b>FY 2013</b>	<b>FY 2014</b>
MRI Scans	801	915	1,030

This is not reasonable. Wake Radiology does not provide any historical MRI utilization for the Alliance mobile MRI at Wake Forest. Therefore, it is impossible to determine if its projections that are based on history are reasonable. Additionally, it is not reasonable to base MRI utilization on “discussions with the Wake Forest site MRI manager.”

**Geographic Location**

Wake Radiology proposes to locate the fixed MRI in Garner. Wake Radiology’s justification for this location includes three arguments.

1. There are currently no fixed MRIs in Garner.
2. The distance to other MRIs
3. The projected population growth of Garner.

**No fixed MRIs in Garner**

Wake Radiology states that “of the existing 13 MRIs in Wake County, there are currently no MRIs located in Garner.” Wake Radiology argues that it will increase MRI access to residents in Garner by placing the proposed fixed MRI in Garner. However, Wake Radiology performed no statistical analysis to demonstrate that Garner needs a fixed MRI. In fact, Garner cannot support an MRI.

Based on 2014 population estimates reported by Claritas, and the location of existing MRIs, it does not appear that Garner will be large enough to support an MRI. Raleigh and Cary will have 42,663 and 48,668 people per fixed MRI in 2014, respectively. Garner will have just 27,666. Please see the table below.

**2014 Population per Fixed MRI**

	<b>Population</b>	<b># of Fixed MRIs</b>	<b>Population / MRI</b>
Raleigh	426,632	10	42,663
Cary	146,005	3	48,668
Garner	27,666	0	
Holly Springs	22,763	0	
Fuquay-Varina	17,653	0	

Source: Claritas

It does appear however, that Holly Springs and Fuquay-Varina could support a fixed MRI scanner. The two areas combined will have 40,416 people in 2014, just slightly less than the number of people per MRI in Raleigh. Wake Radiology does not discuss why it is more appropriate to place the MRI in Garner than in Holly Springs or Fuquay-Varina, neither of which have an existing MRI.

Similarly, an analysis that utilizing the North Carolina state MRI use rate suggests that Garner is not large enough to support a fixed MRI. Please see the table below.

**Estimated 2014 Garner MRI Utilization**

<b>2009 NC Population</b>	<b>2009 NC Weighted MRI Procedures</b>	<b>2009 Weighted NC MRI Use Rate</b>	<b>2014 Garner Population</b>	<b>2014 Garner Weighted MRI Procedures</b>
a	b	c	d	e
9,302,373	991,244	106.56	27,666	2,948

Sources: a – Claritas

b – Proposed 2011 SMFP, Table 9K

c –  $(b) / (a/1,000)$

d – Claritas

e –  $(d/1,000) * (c)$

Clearly, Garner cannot support the number of procedures required to meet the threshold for this fixed MRI on its own. Data in the above table show Garner would be 1,857 weighted MRI procedures short of the required 4,805 weighted procedure threshold for one fixed MRI ( $4,805 - 2,948 = 1,857$ ). Wake Radiology provides no assumption, explanation, or other documentation to show why or how its proposed MRI will draw people away from Raleigh, Cary, or other parts of Wake County to make up the difference in its projected MRI utilization.



### Distance to other MRIs

Wake Radiology states that Garner is located approximately ten miles from the MRIs at WakeMed and between 14 and 16 miles from the MRIs located at Duke Raleigh, Wake Radiology's Raleigh MRI Center, and Raleigh Radiology Cedarhurst. Wake Radiology states that this is too far for residents to travel.

However, the Wake Radiology application omitted the Raleigh Radiology mobile MRI that currently operates approximately eight miles away from Garner, in Clayton. Please see the map in Attachment 1.

Additionally, Wake Radiology did not compare its proposed MRI charge to existing MRI charges. While Duke Raleigh and WakeMed offer higher, hospital based charges, Raleigh Radiology's average MRI charge is currently \$1,792. This is \$379 (17 percent) less expensive than the proposed \$2,171 charge for Wake Radiology in all project years. Raleigh Radiology operates a mobile MRI in Clayton, and a fixed MRI at Cedarhurst. As documented in the map in Attachment 1, these locations are only eight and 16 miles away from the proposed Garner location, respectively. It is not reasonable to expect residents to pay an extra \$379 in order to avoid an 8 or 16 mile drive that takes less than 20 minutes.

### Garner Population Growth

Wake Radiology states that "Garner is a rapidly growing community in Wake County. The population of Garner is expected to increase 15 percent over the next five years. This growth rate is greater than the projected growth rate for Wake County."

However, the table on Wake Radiology's CON application page 21 shows that between 2009 and 2014, the population of Holly Springs is expected to grow 26 percent and the population of Fuquay-Varina is expected to grow 24 percent. During this same time period, the population of Garner is expected to grow only 15 percent. Please see the table below. The applicants did not discuss why it is more appropriate to place the MRI in Garner than in Holly Springs or Fuquay-Varina, both of which are expected to grow faster than Garner. More importantly, in absolute numbers, Fuquay and Holly Springs will have almost twice as many people in 2014.

#### **Southeast Wake County Population Projections**

	<b>2009 Population</b>	<b>2014 Population</b>	<b>Percent Change</b>
Garner	24,023	27,666	15.2%
Holly Springs	18,063	22,763	26.0%
Fuquay-Varina	14,267	17,653	23.7%
Knightdale	7,305	8,181	12.0%
Wendell	4,776	5,176	8.4%

*Source: Wake Radiology CON page 21*

## Population to be Served

Wake Radiology does not document that it will meet the need of the population it proposes to serve. On application pages 108 and 109, Wake Radiology states that it proposes to provide only 3.0 percent of its Garner MRI services to Medicaid and Self Pay beneficiaries. However, according to the US Census Bureau, 9.1 percent of Wake County residents are currently below the poverty level.<sup>1</sup> According to the North Carolina Division of Medical Assistance (DMA), persons below the poverty level are eligible for Medicaid services.<sup>2</sup>

**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 did not document why the geographic location of the proposed MRI in Garner was more effective than locating the MRI in Holly Springs or Fuquay-Varina. Please see a complete discussion in response to Criterion (3) above. Therefore, Wake Radiology did not demonstrate the most effective alternative has been proposed and, thus, is not conforming with this Criterion

Although Wake Radiology discussed retaining the status quo on CON Application pages 89-90, its discussion assumed the continued use of the Alliance mobile MRI scanner at its Garner office. Wake Radiology failed to show that it could not serve the need for MRI services at its Garner Office using its existing mobile MRI scanner, which would involve no capital expenditure. With the start of service by the Alliance fixed MRI at Wake Radiology's Cary office, approximately 40 percent of the historical procedure volume on Wake Radiology's mobile MRI scanner was diverted to the Alliance fixed MRI scanner, and Wake Radiology's mobile MRI scanner became available three days per week: Saturday, Sunday and Tuesday (See Wake Radiology Registration and Inventory, Application Exhibit 16). Consequently, Wake Radiology could reallocate one or more days per week to its Garner location to eliminate the need for contracted mobile MRI service at that location, and or to alleviate capacity constraints at its Raleigh MRI location in Raleigh.

Also, in light of the very low historical MRI utilization rates at Wake Radiology's Wake Forest and Northwest Raleigh locations, the existing Wake Radiology mobile MRI scanner may also be adequate to replace the Alliance Scanners at one or both of those locations. Even if the existing mobile MRI scanner is inadequate to replace all of the Alliance mobile scanners used by Wake Radiology, Wake Radiology failed to consider or address any other allocation of service by its existing mobile MRI scanner other than the proposed allocation, which is likely to result in the mobile MRI scanner becoming severely underutilized, as described above.

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<sup>1</sup> <http://quickfacts.census.gov/qfd/states/37/37183.html>

<sup>2</sup> <http://www.dhhs.state.nc.us/dma/medicaid/basicmedelig.pdf>

Additionally, the application is not conforming to other applicable statutory and regulatory Review Criteria. Therefore, Wake Radiology did not demonstrate the least costly or most effective alternative has been proposed and is thus not conforming to this Criterion. See discussion in Criterion (1), (3), (5), (6), (7), (12), (13a), (13c), and (18a).

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 proposed financial projections unsupported and unreliable following reasons:

- The applicant's projections for utilization are unsupported and unreliable. See discussion above in Criterion (3). Consequently, costs and revenues that are based on the applicant's utilization projections are unreliable.
- The applicant failed to budget adequate expenses for appropriate levels of health manpower. See discussion in Criterion (7).

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 provided no documentation that the proposed project will not result in the unnecessary duplication of existing health service capabilities. As discussed on CON application page 77, the Wake Radiology Garner office is currently served by a Wake Radiology mobile MRI and an Alliance mobile MRI. Wake Radiology provided no evidence that existing demand could not be met with these two MRIs. There is no discussion of capacity constraints or wait times at the Garner site that would necessitate an additional MRI.

Additionally, Wake Radiology provided no discussion on whether or not it will continue to offer services through Alliance at the Garner office. Moreover, Wake Radiology provided no evidence that it will be able to terminate its contract with Alliance, even if it wanted to. If the State awards this competitive MRI to Wake Radiology, their Garner site could potentially have three (3) MRI scanners, where the only concrete data we have shows that 2,323 MRI scans were performed there in fiscal year 2009. This could translate to 774 MRI scans per machine, per year ( $2,323 / 3 = 774$ ).

Therefore, the applicant failed to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities and is non-conforming with Criterion (6).

The application failed to adequately demonstrate the why the geographic location of the proposed MRI in Garner was the most effective alternative. Please see a complete discussion in Criterion (3). Utilization projections that attempt to show that the proposed MRI or its existing MRIs will meet the required performance standards by the third year of the proposed project are misleading and unsupported. Please see a complete discussion in Criterion (3).

Therefore, the applicant failed to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities and is non-conforming with Criterion (6).

**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.***

In Section VII of its application, Wake Radiology does not provide the required Table VII.1 for projected staffing. The application states that Wake Radiology will “hire 2.5 staff for the proposed project, specifically, 2.0 FTE MRI Technologists and 0.5 FTE support staff.” However, Wake Radiology provides no justification for the number of staff it will hire nor does it provide projected salaries for the positions it will add. Therefore, it is impossible to determine if its salary expenses in its proformas are correct.

Additionally, Wake Radiology underestimated MRI staffing requirements. The application did not add FTEs to cover staff positions when employees utilize paid time off (PTO). Therefore, Wake Radiology will either be understaffed when employees utilize PTO or will incur additional costs they did not document. Either way, Wake Radiology has not provided resources needed to meet its proposed staffing plan. Therefore, they did not show evidence of the availability of resources including health manpower and management personnel to meet its proposed staffing.

**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.***

As noted in Criterion (3) and (6) above, Wake Radiology did not document why the geographic location of the proposed MRI in Garner was the most effective alternative. Please see a complete discussion in Criterion (3). Additionally, Wake Radiology did not adequately demonstrate that the proposed MRI or its existing MRIs will meet the required performance standards by the third year of the proposed project. Please see a complete discussion in Criterion (3). Therefore, Wake Radiology’s application is not conforming with Criterion (12).

Additionally, the utilization projections are built on incorrect and unsupported assumptions and therefore fail to demonstrate Wake Radiology’s existing and proposed MRIs will meet the required performance standards or operate above capacity. Therefore, the application does not demonstrate that the capital expenditure of \$1.8 million will not unduly increase the costs of providing health service. Therefore, Wake Radiology’s application is not conforming with Criterion (12).

13. ***The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:***

(a) ***The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;***

According to Section VI, pages 106 and 107 of its CON application, the entire Wake Radiology Garner office served only 4.2 percent Medicaid and Self Pay beneficiaries in FY 2009 and the Wake Radiology Garner Office mobile MRI service served only 3.0 percent Medicaid and Self Pay beneficiaries in FY 2009. However, according to the US Census Bureau, 9.1 percent of Wake County residents were below the poverty level in 2009.<sup>3</sup>

(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***

According to Section VI, pages 108 and 109 of its CON application, the entire Wake Radiology Garner office is projected to serve only 4.2 percent Medicaid and Self Pay beneficiaries in FY 2013 and the Wake Radiology Garner Office mobile MRI is projected to serve only 3.0 percent Medicaid and Self Pay beneficiaries in FY 2013. However, according to the US Census Bureau, 9.1 percent of Wake County residents were below the poverty level in 2009.<sup>4</sup>

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<sup>3</sup> <http://quickfacts.census.gov/qfd/states/37/37183.html>

<sup>4</sup> <http://quickfacts.census.gov/qfd/states/37/37183.html>

**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 the service for which competition will not have a favorable impact.***

As an existing provider of MRI services in Wake County, approval of Wake Radiology's application will not enhance competition by adding a new provider option. The application will not add positive competitive elements of the cost effectiveness, quality, and access to the services proposed, and thus, the application is nonconforming with Criterion (18a).

As a result, the application is non-conforming with this Review Criterion. Please see discussions in Criterion (1), (3), (4), (5), (6), (7), (12), (13a), and (13c).

**SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER**

**10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT**

- (c) **An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:**
- (1) **documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI scanners, will be available and staffed for use at least 66 hours per week;**

Wake Radiology did not show evidence of the availability of resources including health manpower and management personnel to meet its proposed staffing. Therefore, it cannot be assumed that they can provide staffing for the proposed MRI 66 hours per week. Please see the discussion in Review Criterion (7) above.

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

Wake Radiology's projections are based on unsupported assumptions. Please see the discussion in Review Criterion (3) above.

**10A NCAC 14C .2705 STAFFING AND STAFF TRAINING**

- (c) **An applicant proposing to acquire a MRI scanner, including extremity but excluding dedicated breast MRI scanners, shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.**

Wake Radiology did not show evidence of the availability of resources including health manpower and management personnel to meet its proposed staffing. Therefore, it cannot be assumed that they have provided evidence of the availability of two full-time MRI technologists and that one of these technologists shall be present during the hours of operation of the MRI. Please see the discussion in Review Criterion (7) above.

## **Comparative Analysis**

In addition to being non-conforming with CON Review Criteria (1), (3), (4), (5), (6), (7), (12), (13a), (13c), (18a), and administrative rules 10A NCAC 14C .2702(c)(1), 10A NCAC 14C .2703(b)(3), and 10A NCAC 14C .2705(c), Pinnacle Health Services also believes that the application submitted by Wake Radiology offers the least effective alternative of the applications proposed. Specifically, Wake Radiology offers lowest percentage of services to underserved populations, the second highest charge per procedure, and the highest cost per procedure.

Pages two and three of the 2010 SMFP state that, “Equitable access to health care for all the people of North Carolina is a foundation principle for the formulation and application of the North Carolina State Medical Facilities Plan. Barriers to access include, but are not limited to...low income and limited or no insurance...Individuals whose access to needed health services is impeded by any of these barriers are medically underserved.” Access to services is a major concern to the North Carolina State Health Coordinating Council (SHCC) as evidenced by the recent creation of work groups to review and study how best to evaluate this principle. Of all the applications submitted, Wake Radiology proposes to provide the lowest proportion of its services to Self Pay patients and Medicaid beneficiaries.

### **Payor Mix – Second Full FY**

<b>Applicant</b>	<b>Self Pay</b>	<b>Medicaid</b>
Duke Raleigh	3.6%	8.6%
North State Imaging	8.1%	4.8%
Wake Radiology	0.3%	2.7%

*Source: Table VI.15 – Individual CON applications*

In addition to the provision of services for the medically underserved, charges also affect access to healthcare and are of importance to patient, payors, and the public. Reasonable charges ensure that self pay and middle income citizens, who do not qualify for Medicaid, have access to the proposed services. The table below compares charges among the applicants. Wake Radiology proposes second highest charge, and the higher of the two freestanding applications (Wake Radiology and North State Imaging).

### **Average Charge – Second Full FY**

<b>Applicant</b>	<b>Charge</b>
North State Imaging	\$2,046
Wake Radiology	\$2,171
Duke Raleigh	\$2,731

*Source: Proforma Form D – Individual CON applications*



Page three of the 2010 SMFP states that “Cost per unit of service is an appropriate metric when comparing providers of like services for like population.” Operating costs reflect an applicant’s efficiency and give measure of the applicant’s ability to sustain the lower payments made by Medicare and Medicaid payors. As the following table illustrates, Wake Radiology proposes the highest cost per procedure of all three applicants, and is therefore the least effective alternative.

**Cost per Procedure – Second Full FY**

<b>Applicant</b>	<b>Cost/Procedure</b>
Duke Raleigh	\$274
North State Imaging	\$432
Wake Radiology	\$682

**Conclusion**

With the justifications in the above paragraphs, the Agency has standing to find the project non-conforming on eight Statutory Review Criteria and three Administrative Rules:

**Statutory Review Criteria**

1. G.S. 131E-183 (a) (3) – Failure to adequately demonstrate the need the population to be served has for the proposed project.
2. G.S. 131E-183 (a) (4) – Failure to demonstrate that the least costly or most affective alternative has been proposed.
3. G.S. 131E-183 (a) (5) – Failure to demonstrate financial and operational projections are based upon reasonable projections.
4. G.S. 131E-183 (a) (6) – Failure to demonstrate that the project will not result in unnecessary duplication.
5. G.S. 131E-183 (a) (7) – Failure to show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed.
6. G.S. 131E-183 (a) (12) – The proposed construction will unduly increase the cost of providing services.
7. G.S. 131E-183 (a) (13a) and (13c) – Failure to provide significant contribution to underserved populations in comparison to the percentage of the population in the applicant’s service area which is medically underserved.
8. G.S. 131E-183 (a) (18a) – Failure to demonstrate a positive impact upon cost effectiveness, quality, and access.

**Administrative Rules**

1. 10A NCAC 14C .2702 (c) (1) – documentation that the proposed fixed MRI scanner will be available and staffed for use at least 66 hours per week.

2. 10A NCAC 14C .2703 (b) (3) – demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant owns in the proposed MRI service area are reasonably expected to perform 4,805 weighted MRI procedures in the third year of operation.
3. 10A NCAC 14C .2705 (c) – An applicant proposing to acquire a MRI scanner shall provide evidence of the availability of two full-time MRI technologist-radiographers and that one of these technologists shall be present during the hours of operation of the MRI scanner.

The Agency may find other flaws in the application, as a result of its careful evaluation. Thank you for your time and attention to our comments. We understand the difficulties presented in these types of reviews and appreciate your attention to details. Should you have any questions, please do not hesitate to call me.

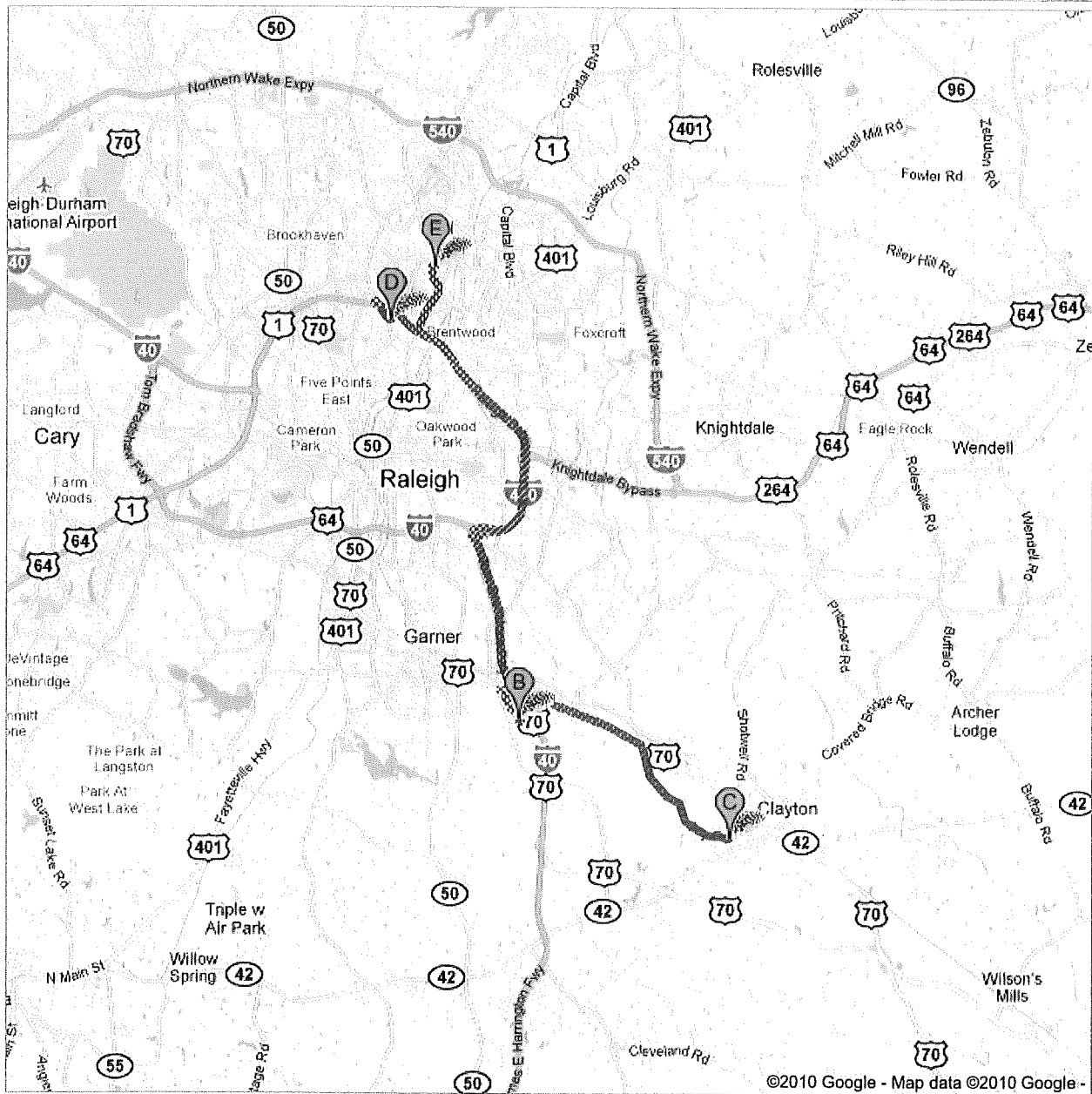
Regards,


*Perry Baker/dl*









Perry Baker  
Secretary  
Pinnacle Health Services, LLC

# Attachment 1

Save trees. Go green!  
Download Google Maps on your phone at [google.com/gmm](http://google.com/gmm)




 1212 Cedarhurst Dr, Raleigh, NC 27609









- 
1. Head **southwest** on **Cedarhurst Dr** toward **Falls of Neuse Rd** go 443 ft  
total 443 ft
  -  2. Take the **2nd left** onto **Falls of Neuse Rd** go 0.7 mi  
About 2 mins total 0.8 mi
  3. Continue onto **Wake Forest Rd** go 1.2 mi  
About 3 mins total 1.9 mi
  -  4. Turn **left** to merge onto **I-440 E** go 6.5 mi  
About 7 mins total 8.4 mi
  -  5. Take exit **16** to merge onto **I-40 E** toward **Wilmington/Benson** go 4.5 mi  
About 5 mins total 12.9 mi
  -  6. Take exit **306** to merge onto **US-70 W** toward **Garner** go 0.6 mi  
About 1 min total 13.5 mi
  -  7. Make a **U-turn** at **Jones Sausage Rd** go 0.2 mi  
total 13.7 mi
  -  8. Take the **1st right** onto **Shenstone Blvd** go 0.2 mi  
total 13.8 mi
  9. At the traffic circle, continue straight to stay on **Shenstone Blvd** go 0.3 mi  
About 1 min total 14.1 mi
  -  10. Turn **left** at **Timber Dr E** go 0.4 mi  
About 1 min total 14.5 mi
  -  11. Take the **1st right** onto **Health Park Dr** go 266 ft  
Destination will be on the right total 14.6 mi

---

Total: **14.6 mi** – about **21 mins**

 300 Health Park Dr, Garner, NC 27529

total 0.0 mi

- 
12. Head **southwest** on **Health Park Dr** go 30 ft  
total 30 ft
  -  13. Turn **left** toward **Health Park Dr** go 348 ft  
total 377 ft
  -  14. Make a **U-turn** go 312 ft  
total 0.1 mi
  -  15. Take the **1st right** onto **Health Park Dr** go 348 ft  
total 0.2 mi
  -  16. Take the **1st left** onto **Timber Dr E** go 0.4 mi  
About 1 min total 0.6 mi
  -  17. Turn **right** at **Shenstone Blvd** go 0.3 mi  
About 1 min total 0.9 mi
  18. At the traffic circle, continue straight to stay on **Shenstone Blvd** go 0.2 mi  
total 1.1 mi
  -  19. Turn **right** at **US-70 E** go 0.2 mi  
About 1 min total 1.3 mi
  -  20. Continue onto **US-70 BUS E** go 3.4 mi  
About 5 mins total 4.7 mi
  - 


21. Turn right at **Guy Rd** go 3.6 mi  
total 8.3 mi  
 Destination will be on the left  
 About 6 mins


**Total: 8.3 mi – about 16 mins**

 300 Guy Rd, Clayton, NC 27520 total 0.0 mi

22. Head **northwest** on **Guy Rd** toward **Laurel Ridge Dr** go 3.5 mi  
total 3.5 mi  
 About 7 mins

-  23. Turn **left** at **US-70 BUS W** go 2.8 mi  
total 6.4 mi  
 About 4 mins

-  24. Merge onto **I-40 W** via the ramp to **Raleigh** go 4.3 mi  
total 10.7 mi  
 About 4 mins

-  25. Take exit **301** for **Interstate 440 Outer/US-64 E** go 0.5 mi  
total 11.2 mi

-  26. Merge onto **I-440 W/US-64 E** go 8.0 mi  
total 19.2 mi  
 Continue to follow I-440 W  
 About 9 mins

-  27. Take the **6 Forke Rd S** exit go 0.1 mi  
total 19.4 mi


-  28. Turn **right** at **Six Forks Rd** go 0.5 mi  
total 19.8 mi  
 About 1 min

-  29. Turn **left** at **Browning Pl** go 325 ft  
total 19.9 mi

-  30. Turn **right** at **Haworth Dr** go 0.1 mi  
total 20.0 mi

-  31. Take the **1st left** onto **Merton Dr** go 194 ft  
total 20.0 mi  
 Destination will be on the left

**Total: 20.0 mi – about 27 mins**

 Raleigh Mri Center: Coates Glen MD total 0.0 mi  
 3811 Merton Drive, Raleigh, NC 27609-6605 - (919) 782-7666

32. Head **west** on **Merton Dr** toward **Haworth Dr** go 194 ft  
total 194 ft

-  33. Turn **right** at **Haworth Dr** go 0.1 mi  
total 0.1 mi

-  34. Take the **1st left** onto **Browning Pl** go 325 ft  
total 0.2 mi

-  35. Take the **1st right** onto **Six Forks Rd** go 0.2 mi  
total 0.4 mi  
 About 1 min

-  36. Slight **right** to merge onto **I-440 E** toward **Beltline** go 1.0 mi  
total 1.4 mi  
 About 1 min

-  37. Take exit **10** for **Wake Forest Rd** go 0.2 mi  
total 1.6 mi

-  38. Turn **left** at **Wake Forest Rd** go 1.2 mi  
total 2.7 mi  
 About 4 mins

39. Continue onto **Falls of Neuse Rd** go 0.7 mi  
total 3.4 mi  
 About 2 mins

-  40. Turn **right** at **Cedarhurst Dr** go 407 ft

Destination will be on the right

total 3.5 mi

**Total: 3.5 mi – about 8 mins**



1212 Cedarhurst Dr, Raleigh, NC 27609

These directions are for planning purposes only. You may find that construction projects, traffic, weather, or other events may cause conditions to differ from the map results, and you should plan your route accordingly. You must obey all signs or notices regarding your route.

Map data ©2010 Google

Directions weren't right? Please find your route on [maps.google.com](http://maps.google.com) and click "Report a problem" at the bottom left.