

02 AUG 2010 4:42

Comments on Wake Radiology MRI Scanner CON Application Project ID # J-8534-10

In accordance with NCGS 131E-185(a1)(1), Johnston Health submits the following comments related to Wake Radiology's application to acquire a fixed MRI scanner in Wake County to be located at its facility in Garner. Johnston Health's comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards" [NCGS 131E-185(a1)(1)(c)]. As such, Johnston Health's comments are organized by the general CON statutory review criteria and specific regulatory criteria and standards, as they relate to the following application:

J-8534-10: Wake Radiology Diagnostic Imaging, Inc. and Wake Radiology Services, LLC (collectively, "Wake Radiology")

BACKGROUND/CONTEXT

As the Agency is aware, subsequent to a competitive review in the 2007 SMFP, Johnston Health was approved to develop a fixed MRI in Clayton. Clayton is a town located on Johnston County's western border with Wake County and is the site of Johnston Health's existing surgery, emergency and diagnostic services in that part of the county, including a radiation oncology center (operated in coordination with Rex-UNC Healthcare) and the fixed MRI that was approved in the 2007 review and made operational in September 2009. In addition to these existing services, Johnston Health is also approved to relocate 27-acute care beds to develop a hospital in Clayton. Clearly Clayton is already a health care destination, particularly for residents of the western part of Johnston County.

Wake Radiology, one of the applicants in this review, provided professional radiology services at Johnston Health through June 30, 2010. Although Johnston Health and Wake Radiology are no longer affiliated, Johnston believes that Wake Radiology and its physicians provided quality care to their patients for many years. However, it should be noted that although Wake Radiology provided the professional services to MRI patients in Johnston County, it did not provide the technical component of the service, which was provided by Johnston Health. This is an important distinction, particularly since Wake Radiology projects to serve a large number of Johnston County patients with the technical and professional component as a result of this application. Specifically, Wake Radiology projects the number of MRI patients from Johnston County at its Garner facility to nearly double, an assumption which cannot reasonably be made, given the availability of scanners in Johnston County (including Clayton).

Johnston Health believes the comments to follow should be viewed in the context provided above. Given the new development of MRI services in Clayton and the unreasonable projected growth in MRI volume for Wake Radiology's Garner site, Johnston Health does not believe the Wake Radiology is conforming with the requisite statutory and regulatory review criteria. Specific comments regarding these are provided in the third section to follow.

INCONSISTENCIES WITH WAKE RADIOLOGY'S PREVIOUS POSITION

In response to a CON application filed November 15, 2008 by Pinnacle Health Services (Project ID # J-8268-08), Wake Radiology filed comments against that application (as did Johnston Health) and eventually filed a contested case petition (09 DHR 3473) on the Agency's decision to approve that application and continued its appeal through the contested case hearing¹. In fact, Wake Radiology has appealed the Final Agency Decision approving Pinnacle's application to the North Carolina Court of Appeals, as of July 2, 2010. Thus, Wake Radiology ostensibly continues to believe that Pinnacle's application for Clayton should not have been approved, that sufficient MRI capacity exists to serve residents of Clayton and the surrounding area. Wake Radiology's application contains numerous statements and projections that are inherently inconsistent with its position in the aforementioned contested case. While some of these are discussed below (with many others apparent in the application), Johnston Health urges the Agency to review documents filed in that case and to discuss issues raised in that case by Wake Radiology, as they have direct bearing on this application and some of the reasons Johnston Health believes it should be disapproved.

As part of its appeal, Wake Radiology argued that Pinnacle's location in Clayton would bring harm to it as a provider of professional services for Johnston Health, because the conversion from a vendor-provided mobile service to a mobile scanner owned by the provider would give Pinnacle more flexibility, expanded availability, expanded hours and expanded days of operation. Thus, Wake Radiology believes that Pinnacle's approved mobile MRI will provide an expansion of services in Clayton. Similarly, Johnston Health began offering fixed MRI services in Clayton in September 2009. As projected in the application, that scanner has not fully "ramped-up" yet, and is expected to increase its volume over the next few years. According to Wake Radiology's testimony in the Pinnacle hearing, it believes that Johnston County had sufficient MRI capacity

¹ In the interest of full disclosure, it should be noted that Johnston Health also filed a Petition for Contested Case Hearing challenging the approval of the Pinnacle Application (09 DHR 3474). This Petition, however, was dismissed prior to the hearing in that matter. Unlike Wake Radiology, however, the positions taken by Johnston Health in that contested case were wholly consistent with those stated in these comments.

before the Pinnacle mobile MRI was approved; thus, with its approval, Wake Radiology must believe that Johnston County has a surplus of MRI capacity. It is therefore inconsistent for Wake Radiology to project in its application to nearly double the number of patients coming from Johnston County to its facility. Wake Radiology has failed to account for the impact of Pinnacle and Johnston Health's MRI scanners and its application is dramatically inconsistent with its position in the recent contested case petition with Pinnacle.

During its appeal of the Pinnacle mobile MRI application, Wake Radiology also critiqued the level of charity care proposed by Pinnacle. In particular, Wake Radiology discussed the statement on page 4 of the Agency findings (Project ID # J-8268-08) regarding Pinnacle's work with Project Access and its proposal to provide one free scan per week, or 52 per year, to Project Access patients. Wake Radiology critiqued Pinnacle in part because it only proposed to perform these scans if its application were approved and because it could have already been providing the scans on its mobile scanner. Only months after making such a critique, Wake Radiology discusses the exact same level of care to Project Access patients on page 110 of its application, even though it clearly has not provided this level of care on its existing mobile MRI service (at least part of which is provided by its own mobile scanner, the revenue for which is completely Wake Radiology's). This fact is demonstrated by on page 144 of the application, the Form C Income Statement for the Garner office, which shows only \$1,026 of charity care for the MRI service in 2009, less than the value of one MRI scan. For the project years, Wake Radiology proposes \$112,896 in charity care for all three years, which is only sufficient for the 52 Project Access scans, based on \$2,171 of gross revenue per scan (per form D, page 145) times the 52 scans. Thus, Wake Radiology proposes to provide only the Project Access scans as charity and no other charity care—not even the \$1,110 it projects to provide in the year prior to the first project year. This proposal is clearly inconsistent with Wake Radiology's critique of Pinnacle for proposing the same level of care.

For additional areas of inconsistency with its previous position regarding the need for additional MRI capacity in the service area, please see Attachment 2, which contains Wake Radiology's comments on the Pinnacle mobile MRI application in Clayton.

ADVERSE IMPACT TO JOHNSTON HEALTH IF WAKE RADIOLOGY'S APPLICATION IS APPROVED

As noted under Criterion 3, Johnston believes that Wake Radiology has overstated its volume projections, particularly in light of the approved Pinnacle mobile MRI and Johnston's recently operational fixed MRI in Clayton. This overstatement of volume projections also results in non-conformity with

Criterion 6, discussed below, and would unnecessarily duplicate existing health services, particularly Johnston Health's existing MRI service. Specifically, Wake Radiology projects its number of MRI scans from Johnston County to grow over 19 percent per year through its third project year. This growth is inconsistent with the historical growth in MRI scans performed in either Wake or Johnston counties over the past several years, and no reasonable basis for this growth rate is provided. If the Agency believes that Wake Radiology's projections are accurate, including its projected scans from Johnston County, then it must also believe that either Johnston County will have a higher MRI growth rate than it has historically (which is not demonstrated in the application) or that Wake Radiology will attract a higher market share of patients from Johnston County to its Garner site than it has historically (which is also not demonstrated in the application). What is discussed in the application is that Wake Radiology projects a higher market share of procedures performed in Wake County than it has historically had at its Garner site. Included in this assumption is the projection that the number and percentage of patients from other counties receiving MRI scans in Wake County will be unchanged—in fact, this assumption is demonstrated by Wake Radiology's patient origin projections, which assume similar (although slightly higher) percentages of patients from Johnston and Harnett counties. This assumption is critically flawed because it completely ignores changes in the service area that will negatively impact the patients that will come into Wake County for MRI scans. These changes and their impact are discussed in the following paragraphs.

RECENTLY APPROVED PINNACLE MOBILE MRI APPLICATION

Wake Radiology first ignores that two new MRI providers have recently begun operating in Johnston County, specifically in Clayton, which is near the Johnston-Wake County border. One of the providers, Pinnacle Health, was approved to develop a mobile MRI service in Wake and Johnston counties, including Clayton. This CON approval was contested by Wake Radiology and was the subject of an administrative hearing earlier this year. Although that case has been appealed to the NC Court of Appeals, the Final Agency Decision was to approve the Pinnacle application. In fact, at the time the Wake Radiology application was filed, the Pinnacle decision had not yet been appealed to the NC Court of Appeals; thus, the most recent activity in that case was the approval of the Pinnacle application. This fact is known to Wake Radiology because it was the Petitioner in the Pinnacle case; yet, this fact was completely and inexplicably ignored in the Wake Radiology application. In appealing the Pinnacle application, Wake Radiology argued that sufficient MRI capacity existed in Johnston County (through the two fixed scanners owned by Johnston Health) and that the Pinnacle mobile MRI capacity was not needed. Yet in this application, filed only months after Wake Radiology made those arguments, it

assumes that its Garner office will provide MRI scans to nearly two times as many Johnston County residents as it has historically. This assumption is clearly unreasonable for an applicant that believes the Johnston County market is already sufficiently served by MRI scanners.

RECENTLY OPERATIONAL JOHNSTON HEALTH MRI LOCATED IN CLAYTON

Wake Radiology also ignores the newly approved fixed MRI scanner owned by Johnston Health and located in Clayton. As former providers of professional services for Johnston Health's radiology services, including MRI, Wake Radiology is fully aware of the presence of Johnston Health's scanner, having interpreted images performed on it even after its application was filed. The MRI scanners are very similar, if not identical, in type and configuration, which is logical since Wake Radiology had input on what type of scanner Johnston Health purchased and since the scanner was operationalized within the past year. Wake Radiology also has access to records of the number of scans performed on the Johnston Health scanner, since it billed patients for the professional component of the MRI scans. Yet no mention of this new scanner or its impact on the number of patients leaving Johnston County to travel into Wake County is even mentioned in the application. This inconsistency with Wake Radiology's recent (and ongoing) position is discussed in greater detail above.

CONSISTENCY WITH RECENT AGENCY MRI DECISIONS FOR JOHNSTON COUNTY

In order to maintain consistency with its previous findings, Johnston Health believes the Agency should review its findings on both the Johnston Health MRI scanner (J-7900-07) as well as the Pinnacle mobile MRI scanner. On page three of the Johnston Health findings, a quote from the approved application reads,

"According to state patient origin data for MRI, compiled by the Medical Facilities Planning Section, in 2005, 5,491 Johnston County residents received an MRI scan outside of the county. This volume alone is sufficient to generate a need for at least one additional scanner. The substantial number of patients receiving services outside the county can be attributed to JMHA's capacity constraints, as well as the lack of MRI services in a key population center of Johnston County, Clayton." [Emphasis added]

See Agency findings for J-7900-07 at page 70.

As noted in the Johnston Health application and this portion of the Agency findings, part of the need identified for a fixed MRI in Clayton was the number of Johnston County residents leaving the county for MRI scans, particularly from the western area of the county (Clayton). In other words, the Agency approved

Johnston Health for a second MRI scanner to obviate the need for as many Johnston County patients to leave the county for MRI scans as they have in the past. The Johnston Health application was fully supported by Wake Radiology, as Johnston Health’s radiologists at the time; yet no mention of this application, the recently operational MRI scanner or any consideration for the fact that it was proposed to provide a location in Clayton so that residents of the county, particularly the western part of the county, would not have to leave Wake County for MRI service.

FINANCIAL IMPACT

These omissions not only cause the Wake Radiology application to be flawed (see discussion under the applicable review criteria below), but they also show that Johnston Health will be harmed financially if the Wake Radiology application is approved. When Johnston Health proposed a second fixed MRI scanner for Clayton, it proposed to invest more than \$2 million of capital to better serve the health care needs of Johnston County. As a hospital authority, Johnston Health has no profit incentive driving its decisions; however, since it is self-supporting, it must ensure that it will be able to continue offering its services to the residents of Johnston County. Between 2009 and 2014, Wake Radiology projects the number of scans it performs from Johnston County to increase by 738 (see detailed discussion under Criterion 3 below). If the Agency approves the Wake Radiology application because it believes Wake Radiology is capable of achieving this growth, and if that growth were to occur (although Johnston Health does not believe it is reasonable), it will result in 738 fewer scans performed on Johnston County residents in Johnston County, since they would be performed at the Garner facility. When the Johnston Health’s Clayton MRI application was approved, there were no other MRI providers in Johnston County and Wake Radiology only operated a mobile MRI scanner at its Garner facility. With the approval of the Pinnacle mobile MRI application, another provider has been added in Clayton, and it is even more imperative that Johnston Health’s MRI utilization assumptions, including the portion of the findings excerpted above, be supported by future Agency decisions. If Wake Radiology’s application is approved, and if Wake Radiology is successful at preventing 738 Johnston County patients from receiving their MRI scan in Johnston County, Johnston Health would experience considerable harm. Specifically, if Johnston Health’s newly operational MRI scanner in Clayton performed 738 fewer scans, the financial impact would be more than \$1 million in lost gross revenue, as shown in the following table.

<i>Gross Revenue per Scan (PY 3)</i>	<i>Total Scans (PY 3)</i>	<i>Total Gross Revenue</i>	<i>Total Scans less 738 Wake</i>	<i>Gross Revenue for 738</i>
--------------------------------------	---------------------------	----------------------------	----------------------------------	------------------------------

			<i>Radiology Scans</i>	<i>Scans</i>
\$1,364	3,515	4,795,287	2,777	\$1,006,632

Even if the impact to Johnston Health is only half the number of additional scans Wake Radiology projects to capture from Johnston County, the financial impact would still exceed \$500,000, which would have a significant and detrimental impact to Johnston Health and the residents of Johnston County. As noted in the Wake Radiology application, the economic turmoil of the past two years has had a detrimental impact on health care providers as well. While Wake Radiology believes this impact is over for MRI providers in Wake County (see discussion under Criterion 3 below), Johnston Health more realistically understands that the economy will not turn around immediately. Johnston Health believes the negative economy has also impacted its utilization, including its MRI utilization. As shown on page 8 of the findings for the Clayton MRI scanner, Johnston Health projected 2,790 unweighted MRI scans in its first project year. Since opening in September 2009 through June 2010, Johnston Health performed 961 MRI scans at its Clayton site, which equates to an annualized total of 1,153 scans. Thus, it can reasonably be expected that Johnston Health will fall short of its projected number of scans for Clayton by approximately 1,600 scans. As the economy improves, this volume will increase; however, at least some of this volume shortfall can likely be attributed to the development of Pinnacle’s mobile MRI site in Clayton, which, as noted above, had not been developed at the time of Johnston Health’s MRI application. If the economy and the development of Pinnacle’s mobile MRI can have an impact on Johnston Health’s MRI volume, then certainly the development of a full-time, fixed MRI scanner in Garner, just a few miles away from Clayton, will have a negative impact on Johnston Health’s MRI volume. As shown in the audited financial statements for FY 2009 (Attachment 1), Johnston Health experienced a net operating loss of more than \$3 million last year. If the proposed Wake Radiology application is approved, Johnston Health will lose additional revenue needed to ensure continuing care to Johnston County residents. Johnston Health is a safety net hospital, the sole provider in the county and needs revenues from well-reimbursed services like MRI to offset losses from other services that need to be provided but are reimbursed below costs. The analysis above clearly indicates that Johnston Health—and the residents of Johnston County—cannot afford to lose additional MRI scans that it was approved to provide to Johnston County residents on its Clayton scanner.

In addition to the financial impact, Johnston Health would also be harmed if the Agency approved Wake Radiology’s application because of the inconsistency between the Agency’s decision to approve Johnston Health and its approval of Wake Radiology. As discussed in the previous paragraph, Johnston Health was

approved to develop its fixed MRI scanner in Clayton in part because of the need to serve Johnston County residents within their home county. The need to provide reasonable access to patients is a central theme in the CON law as well as multiple Agency findings. The Wake Radiology application proposes the opposite: that more patients will leave Johnston County and they will specifically seek care at Wake Radiology's Garner facility. This is inconsistent not only with the CON findings approving applications that improve access for patients within their home county, it is also inconsistent with the Agency's approval of Johnston Health's application to do just that.

Moreover, the approval of the Wake Radiology application would undercut the Agency's own decisions with respect to both the Clayton (Johnston Health) and Pinnacle MRI to the extent that such an approval would—as a practical matter—render it impossible for either provider to achieve the projections contained in their applications. In each case, these projections formed the very basis of the Agency's approval of those applications. Thus, in reality, by approving the Wake Radiology application, the Agency would almost necessarily be creating a situation that fosters the unnecessary duplication of health services and one which erodes the long term feasibility of these CON-approved health services. This is the essence of inconsistency: inconsistency with the Agency's own prior decisions, inconsistency with sound health planning, and inconsistency with the bedrock principles of the CON process set forth in N.C. Gen. Stat. § 131e-175.

The approval of Wake Radiology's application would also harm Johnston Health because such a decision would be inconsistent with other Agency findings, specifically those in which an applicant proposed growth in future although it had experienced declining volume in the past. Although the Wake Radiology application appears to project modest growth through the use of market growth and market share gains, it is actually projecting its volume to grow substantially in the future, even though its volume declined in the past year—unlike the positive growth for the rest of Wake County. Clearly Wake Radiology cannot reasonably project its volume to grow in the future without performing the necessary analysis to support such a change; yet, the application fails to account for the two new MRI providers in its service area (Clayton) and how their presence in the market will negatively impact its future volume. As such, an approval of the Wake Radiology application would harm Johnston Health by being inconsistent with Agency findings that required applicants to account for such factors.

COMMENTS RELATING TO STATUTORY AND REGULATORY REVIEW CRITERIA

- (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.*

The Wake Radiology application contains critical errors in its need calculations, specifically its volume projections, that cause it to be non-conforming with this criterion, as discussed below.

1. The utilization methodology is not conservative and is unreasonable.

Starting on page 76, Wake Radiology presents its methodology for projecting utilization. It begins with the historical and projected MRI volume in Wake County, calculates its historical market share at the Garner office, then projects the future market share to determine its expected future volume. The application presents the resulting projections as "conservative," since the overall volume growth is projected to be less than the historical trend and since the market share percentage increases seem small. There are several problems with these assumptions however, and, as demonstrated by an examination of the total percent growth projected by these assumptions, they are not reasonable, as explained below.

- a. The methodology is inconsistent with the patient origin assumptions. The application calculates MRI scans performed in Wake County without regard to the origin of the patients comprising those scans. Projecting a continued increase in this number without regard for patient origin assumes that patients from other counties will continue seeking care in Wake County at that projected growth rate. As a result, any projection of future MRI volume performed in Wake County should examine activity in neighboring counties that have historically provided patients to Wake County providers, in order to more fully assess the impact of these activities on the volume of MRI scans performed in Wake County. This is particularly true for a non-hospital site located on the border of another county where much MRI activity has recently occurred. While Wake County MRI providers as a whole may continue to attract patients from other counties for MRI service, it is unreasonable for Wake Radiology to fail to consider whether the factors in its service area will enable it to attract patients from nearby counties at the same rate. Clayton, in Johnston County, is only a few miles from Wake Radiology's

proposed Garner location. In the past two years, two additional MRI scanners have been added in Clayton: one, a mobile MRI site operated by Pinnacle Health Services, which is approved to replace the vendor-owned scanner with its own scanner, and; two, a fixed MRI owned by Johnston Health and located at its facility in Clayton. Wake Radiology itself opposes the Pinnacle application and does not believe there is a need for additional MRI capacity in Clayton. It is therefore inconsistent to project a growth in the number of patients from other counties, particularly Johnston, that seek care at Wake Radiology's proposed Garner fixed MRI, since there is available capacity on Johnston Health's new scanner and since Wake Radiology believes the approved Pinnacle scanner will add even more (unneeded) capacity. The table below shows the numeric result of Wake Radiology's assumptions as they relate to patient origin and the projected number of scans from each county.

<i>Historical Patient Origin</i>			<i>Projected Patient Origin</i>		
<i>County</i>	<i>Percentage</i>	<i>Scans (2009)</i>	<i>County</i>	<i>Percentage</i>	<i>Scans (2014)</i>
Wake	59.0%	1,371	Wake	60.5%	2,689
Johnston	33.1%	769	Johnston	33.9%	1,507
Harnett	5.5%	128	Harnett	5.7%	253
Other	2.5%	58	Other	0.0%	0
Total	100.1%	2,323	Total	100.1%	4,444

The table above shows several ways in which Wake Radiology's assumptions result in unreasonable projections. First, the total growth in scans from 2009 to 2014 (the third project year) is 91.3 percent $[(4,444 - 2,323) \div 2,323 = .913]$, nearly double the volume in that five year period. On an annual basis, this equates to 18.3 percent annual growth $(.913 \div 5 \text{ periods} = .183)$, which is clearly much higher than any recent historical MRI volume growth experienced in Wake County, and is more than double the historical five year CAGR for Wake County. In addition, the table shows the unreasonable growth in the number of scans from Johnston County in particular. While the location of Wake Radiology's Garner site on the Johnston County border has been the likely factor in enabling it to capture patients from Johnston County historically, it is not reasonable to expect the number of patients from Johnston County to grow 95.9 percent in the five year period $[(1,507 - 769) \div 769 = .959]$, or 19.2 percent annually $(.959 \div 5 \text{ periods} = .192)$. In its comments against the Pinnacle

mobile MRI application (Project ID # J-8268-08), Wake Radiology commented that Pinnacle's projected growth at its Clayton site was an unreasonably high 10.3 percent CAGR:

"The total scan volume is projected to grow from 668 to 988 in the same timeframe, a CAGR of 10.3 percent. Clearly, the utilization projections are not as conservative as the 2.7 percent shown in the application narrative."

See Wake Radiology comments in Attachment 2 at page 3.

Based on its own beliefs about the future growth of Johnston County MRI volume, in Clayton in particular, Wake Radiology cannot believe that its projected 19.2 percent annual growth is reasonable, given that it did not believe Pinnacle's 10.3 percent growth rate to be reasonable, and now that Pinnacle's application has been approved, the Final Agency Decision has upheld its original approval, and the Johnston Health MRI scanner has become operational.

- b. The methodology unreasonably assumes the growth in Wake County will be mirrored at its facility. On page 76 of the application, Wake Radiology discusses the most recent year of MRI volume growth for Wake County providers, citing this growth as a sign of economic recovery and a contrast to the previous year's decline in MRI use rate in Wake County. While the one year trend for all Wake County providers may have been positive for 2009, such was not the case for Wake Radiology's existing Garner site. This fact is shown on page 99 of the application—the table shows a decline in volume at Garner from FY 2008 to FY 2009, from 2,483 scans to 2,323, a *decline* of 6.4 percent $[(2,323 - 2,483) \div 2,483 = -.064]$. Thus, while Wake County volume grew from FY 2008 to FY 2009, Wake Radiology's Garner site did not; it is unreasonable to assume that Wake Radiology's Garner volume will suddenly begin to mirror Wake County's growth when it has not historically done so.

The difference between Wake County's overall historical growth and Wake Radiology's Garner site's historical growth is not unexpected and should have been accounted for by Wake Radiology. As explained above, Garner is on the border of Johnston County and while that has historically brought Wake Radiology some patients from Johnston County, that number can

reasonably be expected to diminish as a result of Pinnacle's mobile MRI and Johnston Health's new fixed MRI scanner, both in Clayton. In fact, Wake Radiology itself believes that the historical decline in overall volume at the Garner site is attributable to the Pinnacle mobile coming to Clayton. In the comments and related case against the Pinnacle mobile MRI application, it was clear that Wake Radiology believe that that the volume at its Garner facility (i.e. the site of the existing mobile MRI and proposed fixed MRI) as well as Johnston Health's existing site in Smithfield and its approved site in Clayton had been and would be negatively impacted by the approval of Pinnacle's mobile site in Clayton. In other words, Wake Radiology believed the following regarding Pinnacle's presence in Clayton:

1. Wake Radiology's overall volume declined following Pinnacle's entrance into the Clayton market and is expected to continue to decline;
2. Wake Radiology's percentage of underserved payors, such as Medicare, increased, corresponding to a decrease in its volume of commercial payors, such as Blue Cross, following Pinnacle's entrance into the Clayton market; this trend is expected to continue.

Both of these factors were presented by Wake Radiology – *only a few short months ago* in a contested case hearing conducted in January 2010. Yet even though Wake Radiology argued that Pinnacle's mobile site in Clayton had already caused Wake Radiology's mobile MRI volume at its Garner office to decline and its MRI payor mix at the Garner office to be negatively impacted, and even though it argued that this trend would continue if Pinnacle were approved, *Wake Radiology projected its volume to continue to increase each year*, even during the interim period prior to the development of the proposed fixed MRI, and Wake Radiology projected no change in its payor mix. The Final Agency Decision in the Pinnacle case was to approve the CON and allow Pinnacle to develop a mobile MRI to serve Clayton; however, Wake Radiology's application is completely silent regarding the impact of this approval on its Garner office, even though it argued vehemently only six months ago that Pinnacle's approval would have a negative impact.

In fact, based on the fact that Wake Radiology's volume at its Garner office did decline from 2008 to 2009, Pinnacle's presence in the market was likely a factor in this decline, as expressed by Wake Radiology. However, the application fails to consider the ongoing impact of Pinnacle on its volume projections, neither does the application address the historical decline at the Garner facility. The application attributes the decline in MRI use rate in Wake County solely to the economic downturn, as discussed on pages 64 and 65. Even if the economic downturn were responsible for the decline in the Wake County MRI use rate in 2008, and the economic recovery were evidence of the increase in use rate in 2009, neither of these factors explains why the Wake Radiology Garner facility's volume declined in 2009. Clearly the addition of new providers in Clayton had an impact on the Garner volume; yet Wake Radiology fails to account for this ongoing impact in the future, particularly for its Johnston County patient volume.

- c. Wake Radiology provides no basis for its projected volume increases during the interim years (FY 2010 and FY 2011); therefore, the volume it projects for these years and the subsequent years (which is based on the interim years) is unsubstantiated and unreasonable. As discussed in the preceding point, Wake Radiology states that its Garner volume will grow as a factor of the overall Wake County growth; however, that is unreasonable given the latest (and only) historical period of volume provided in the application, which shows a decline from FY 2008 to FY 2009. In fact, Wake Radiology does not provide any volume data for any part of FY 2010, even though two-thirds (eight months) of FY 2010 had passed. While Wake Radiology may argue that year-to-date FY 2010 data are not expressly required, they may certainly be provided if they are helpful in demonstrating need. In any case, there are no more recent data provided to demonstrate why it is reasonable to expect volume for FY 2010 and FY 2011 to increase, given the historical trend at Wake Radiology's Garner site and its president's statements about the negative impact expected from Pinnacle.
- d. Wake Radiology's volume projections are not supported by and are inconsistent with the physician support letters. On pages 80 through 82, Wake Radiology discusses the letters of support it received, and in multiple places throughout the application,

Wake Radiology indicates that these letters support its market share assumptions and volume projections. However, the letters of support speak only to Wake County, not Johnston, Harnett and others. Even the letters from physicians in Johnston County include the same language as letters from the other physicians, stating that the proposal “*will offer residents of Garner and southwest Wake County*” MRI services and that it will eliminate the “*need to drive to Raleigh or Cary to obtain an MRI scan.*” Clearly this language refers only to referrals for and the need of residents of the Garner area in Wake County, since patients in Clayton, Smithfield or other parts of Johnston County do not have to drive to Raleigh or Cary, but already have access to local MRI service. The letter continues to refer to Wake County, stating that the “*proposed MRI scanner will provide care for all residents of Wake County*” but does not refer to Johnston, Harnett or any other counties.

Even though the physician letters of support discuss Wake County patients, and not patients from other counties, Wake Radiology’s application projects that *nearly 1,800 patients, or 40 percent*, will come from Johnston and Harnett counties. Clearly this projection is not based on the physician letters and the letters do not support such an assumption.

- e. Wake Radiology’s discussion of need includes analysis of Wake County only, not Johnston or Harnett. Starting on page 59 of the application, Wake Radiology discusses the need in Wake County, citing the Wake County population growth rate, not any other counties. The table on page 63 shows the breakdown of the primary service area by ZIP code, and although the Clayton and Willow Spring ZIP codes (which include portions of both Wake and Johnston counties) comprise only 16.2 percent of the total population, Wake Radiology projects 33.9 percent of its patients to come from Johnston County. As shown in the table below, the population of the Clayton and Willow Springs ZIP codes is actually split between Johnston and Wake counties.

ZIP Code	Total Population	Wake County Total	Wake County %	Johnston County Total	Johnston County %
ZIP Code 27520 Clayton	35,801	977	2.7%	34,824	97.3%
ZIP 27592	13,568	7,812	57.6%	5,756	42.4%

Willow Springs					
----------------	--	--	--	--	--

Source: Claritas data for 2010, accessed July 30, 2010.

As shown by the Claritas data (the source used by and available to Wake Radiology), some the Clayton and most of the Willow Springs ZIP code is in Wake County. Assuming these data as a proxy for 2009, 33,414 residents of ZIP 27520 ($34,341 \times .973 = 33,414$) and 5,767 residents of ZIP 27592 ($13,601 \times .424 = 5,767$), for a total of 39,181, reside in Johnston County. These residents represent only 13.2 percent of the total primary service area population, yet Wake Radiology projects these residents to account for 33.9 percent of its patients. This disparity indicates two possible underlying (but unwritten) assumptions: either Wake Radiology projects the use rate for Johnston County residents to grow at a faster rate than Wake County, or it projects a greater percentage of Johnston County residents to leave Johnston County to come to the Wake Radiology facility. Neither of these assumptions is supported by the application, and Wake Radiology's position has been that the volume has been and will continue to be negatively impacted by the development of MRI capacity in Clayton. Moreover, given the development of the two MRI's in Clayton, which proposed to improve access to Johnston County residents, particularly in the portion of the county closest to Wake County and Garner, there is already sufficient MRI capacity to serve Johnston County patients from these ZIP codes.

The application's analysis continues to discuss the Wake County MRI use rate, Wake County MRI utilization, Wake County mobile MRI use, the location of fixed MRI scanners in Wake County, demographics of Wake County municipalities, and the distance of Wake County municipalities from existing MRI scanners in Wake County. In fact, the entirety of Section III.1, which discusses the need for the proposed service, focuses exclusively on Wake County. Yet, the applicant's patient origin projects 40 percent of its patients to come from other counties, primarily Johnston. It is also inconsistent to examine the number of MRI scanners within a five-mile radius of various Wake County municipalities to show comparative need, without also showing the two new MRI scanners that provide local access to residents of the portion of Johnston County from which Wake Radiology projects to draw patients.

While the applicant may argue that its patient origin assumptions are based on its historical practice at its Garner office, it is not reasonable to expect the same growth in patients from Johnston County as from Wake County, given the applicant's focus on the need in Wake County, the physician referral letters discussion of only Wake County and the recent development of two new MRI providers in Clayton, one of which already has had some negative impact on Wake Radiology, per its previous position.

2. Wake Radiology's projected volume on its existing mobile MRI scanner is also unreasonable.

On page 50, Wake Radiology begins discussing its methodology for projecting volume for its existing mobile MRI scanner. As an existing mobile MRI scanner, located in the service area and owned by the applicant, Wake Radiology is required to reasonably project that it will perform 3,328 weighted MRI scans in the third year. While Wake Radiology projects the requisite number, its assumptions and methodology for doing so are unreasonable.

- a. On page 50, Wake Radiology states that its existing fixed MRI scanners at its Raleigh office are operating "above practical capacity." Although never defining "practical capacity," the application refers to the 4,805 planning threshold. This number, 4,805 is never referred to as the "practical capacity" for MRI scanners; in fact, the SMFP clearly shows that number as 70 percent of the total capacity of 6,864, as shown by the applicant on pages 60 and 100. On page 34, the applicant projects a total of 9,744 weighted MRI procedures in year three on its fixed MRI scanners at its Raleigh office; on page 51, it projects 1,406 weighted MRI procedures in year three on its mobile MRI scanner, for the Raleigh office site. Thus, for year three, it projects a total of 11,150 weighted MRI scans for its two fixed and one mobile MRI scanners. If the applicant only used its two fixed MRI scanners to perform these scans, then it would be performing 5,575 weighted scans per MRI, which is 81 percent of the actual capacity. Thus, Wake Radiology would be operating between 70 and 81 percent of capacity, if it only used its fixed MRI scanners at its Raleigh office. It must also be noted that this capacity is based on the minimum 66 hours of operation per week; thus, Wake Radiology's statements on page 50 regarding its desire to "decompress capacity constraints" and

“facilitate scheduling flexibility for increased patient satisfaction” have not been demonstrated in the application. This factor is important to consider, given that Wake Radiology must rely heavily on shifting its Raleigh office volume to the mobile MRI scanner in order to demonstrate that it would continue to be well utilized if the Garner application were approved.

- b. The applicant’s projected utilization for the Northwest Raleigh and Wake Forest sites is discussed on pages 51 through 53. For both of these sites, the applicant fails to provide any analysis or historical data to support the projected volume increase. In fact, the historical data provided for the Northwest Raleigh office, shown on page 47, indicates that only 22 weighted scans were provided at that site in FY 2009 using the mobile scanner. Thus, the application projects to grow from 22 weighted scans to 1,048 weighted scans by the third project year, based on “current mobile utilization at this site, current referral patterns and discussions with WRNWRO’s MRI manager.” For the Wake Forest site, the applicant projects an identical number of unweighted procedures by year three as it did for Northwest Raleigh. No analysis is provided in the application, other than the statement that FY 2009 volume for the mobile MRI at Wake Forest was 180 procedures. For both sites, Wake Radiology relies on projected “scans per day,” which, given the historical volume at both sites, make the volume projections appear more conservative than they are. Wake Radiology previously critiqued Pinnacle’s use of this methodology—in comments filed on the Pinnacle mobile MRI application (J-8268-08), Wake Radiology stated,

“In order to examine the reasonableness of Pinnacle’s projections, the total annual volume growth must be analyzed, since data for “scans per day” is not available publicly and cannot be used for comparison purposes. As stated above, Pinnacle projects growth in total scans per year for Wake Forest and Clayton to be 9.2 and 10.3 percent, respectively. These growth rates are considerably higher than the growth rates for Wake and Johnston counties as well as for North Carolina as a whole.”

See Wake Radiology comments in Attachment 2 at page 3.

Similarly, Wake Radiology is now projecting its volume to grow at an unreasonably high growth rate for Wake Forest and Northwest Raleigh, without any historical basis for that growth.

Perhaps the simplest way to understand the reason for Wake Radiology's aggressive mobile MRI projections is to examine the table on page 47 of the application. As shown, in 2009 all but 43 of the 3,560 weighted MRI scans provided by Wake Radiology's mobile MRI were for sites that its mobile MRI will no longer serve in the future if the application is approved. In other words, Wake Radiology must "replace" the 2,141 weighted scans it provided at its Garner office that would be served by the proposed fixed MRI and the 1,375 weighted scans provided at its Cary office that is now served by an Alliance-owned fixed MRI scanner. Note that Wake Radiology does not provide the projected volume for the Cary site in its application.

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

As discussed under the section on adverse impact to Johnston Health and under Criterion 3, two new MRI scanners are operating in Clayton, in Johnston County, which is within Wake Radiology's service area and from which it projects to serve patients. Wake Radiology appealed the approval of Pinnacle's mobile scanner, stating that its approval would negatively impact its volume, yet the application does not provide any analysis the effect of Pinnacle or Johnston Health's new scanners will have on its proposed project. Given the capacity of these scanners and Wake Radiology's failure to discuss them in its application, the applicant has failed to demonstrate that it will not unnecessarily duplicate the existing and approved health service facilities in the service area.

REGULATORY CRITERIA

10A NCAC 14C .2702

- (c) *An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall provide the following information:*
- (8) *for each location in the MRI service area at which the applicant or a related entity will provide MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of unweighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

Wake Radiology fails to respond to this rule for its Cary facility. The applicant indicates that it confirmed with Mike McKillip that this rule did not apply to its Cary office, since the fixed MRI that providers services there is not owned by Wake Radiology. However, unlike the performance standard portion of the rules, this rule does not refer to the scanner's ownership. Rather, the rule requires the applicant to project volume for each location at which it provides MRI services. Wake Radiology provides MRI services at its Cary office. Therefore, it is required to respond to this rule for its Cary office and is non-conforming with this rule as a result of its failure to do so.

This failure also relates to Criterion 3 and Wake Radiology's attempt to demonstrate need. As expressed in the application and each of the physician support letters, residents of Garner and southeast Wake County currently seek care in Cary. Since Wake Radiology provides MRI services in Cary, and particularly because it has rather recently began this service, the impact of its proposed expansion of MRI services in Garner is related to its provision of MRI services in Garner.

- (9) *for each location in the MRI service area at which the applicant or a related entity will provide services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual number of weighted MRI procedures to be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of the first three years of operation after completion of the project;*

Wake Radiology fails to respond to this rule for its Cary facility. The applicant indicates that it confirmed with Mike McKillip that this rule did not apply to its Cary office, since the fixed MRI that providers services there is not owned by Wake Radiology. However, unlike the performance standard portion of the rules, this rule does not refer to the scanner's ownership. Rather, the rule requires the applicant to project volume for each location at which it provides MRI services. Wake Radiology provides MRI services at its Cary office. Therefore, it is required to respond to this rule for its Cary office and is non-conforming with this rule as a result of its failure to do so.

This failure also relates to Criterion 3 and Wake Radiology's attempt to demonstrate need. As expressed in the application and each of the physician support letters, residents of Garner and southeast Wake County currently seek care in Cary. Since Wake Radiology provides MRI services in Cary, and particularly because it has rather recently began this service, the impact of its proposed expansion of MRI services in Garner is related to its provision of MRI services in Garner.

- (10) *a detailed description of the methodology and assumptions used to project the number of unweighted MRI procedures to be performed at each location, including the number of contrast versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus outpatient procedures;*

Wake Radiology fails to respond to this rule for its Cary facility. The applicant indicates that it confirmed with Mike McKillip that this rule did not apply to its Cary office, since the fixed MRI that providers services there is not owned by Wake Radiology. However, unlike the performance standard portion of the rules, this rule does not refer to the scanner's ownership. Rather, the rule requires the applicant to project volume for each location at which it provides MRI services. Wake Radiology provides MRI services at its Cary office. Therefore, it is required to respond to this rule for its Cary office and is non-conforming with this rule as a result of its failure to do so.

- (11) *a detailed description of the methodology and assumptions used to project the number of weighted MRI procedures to be performed at each location;*

Wake Radiology fails to respond to this rule for its Cary facility. The applicant indicates that it confirmed with Mike McKillip that this rule did not apply to its Cary office, since the fixed MRI that providers services there is not owned by Wake Radiology. However, unlike the performance standard portion of the rules, this rule does not refer to the scanner's ownership. Rather, the rule requires the applicant to project volume for each location at which it provides MRI services. Wake Radiology provides MRI services at its Cary office. Therefore, it is required to respond to this rule for its Cary office and is non-conforming with this rule as a result of its failure to do so.

10A NCAC 14C .2703

- (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:*
- (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;

Although Wake Radiology projects each of its fixed MRI scanners to perform 4,805 weighted procedures in the third year, its utilization is not based on reasonable assumptions. Please see the discussion under Criterion 3.

- (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*

Wake Radiology projects that its mobile MRI scanner will perform more than 3,328 scans in the third project year; however, as explained under Criterion 3 above, those projections are not based on reasonable assumptions. In fact, the applicant provides essentially no assumptions whatsoever for the utilization projections for its Wake Forest and Northwest Raleigh sites. The projections for these two sites in particular are problematic for several reasons:

1. The sites began operating in FY 2009; Northwest Raleigh operated for only one month of that year (page 52). In the time that the two sites were operating in 2009, Wake Forest provided only 180 mobile scans (page 53) and Northwest Raleigh only 20 mobile scans (page 52). Clearly, this volume is not a basis for the approximately 1,000 scans projected by the applicant for both sites.
2. No volume is provided for any of Wake Radiology's sites, including these two new mobile sites, for the time period from October 2009 to June 15, 2010, when the application was filed. Regardless of whether the applicant is required to provide these data, without its inclusion in the application, it cannot be a basis

of support for the projected volume and one can assume that the volume is minimal.

3. The application provides no volume for the intervening years, 2010 and 2011. Without a projected growth trend for the intervening years, the application projects to go from 20 scans to 728 at Northwest Raleigh (from 2009 to 2012) and from 180 scans to 728 at Wake Forest (from 2009 to 2012).
4. The projected unweighted scan volume is identical for both Wake Forest and Northwest Raleigh. Although the projected weighted scan differs due to differences in contrast ratios, it is unlikely that the scan volume for both sites would be identical. To project as such is a clear indication that no analysis of the need of the population, demographics, MRI use rates, market share or any other analysis was performed to arrive at the projected volume.

Since the applicant provides no basis for its projections and based on the flaws enumerated above, the application is non-conforming with this rule.

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

Although Wake Radiology provides utilization projections for its fixed and mobile MRI scanners (with the exception of the fixed MRI scanner for which it bills patients at its Cary facility), it does not provide data supporting the methodology for its projected mobile MRI volume, particularly for its Wake Forest and Northwest Raleigh sites. Please see the discussion above.

Attachment 1

**JOHNSTON MEMORIAL HOSPITAL AUTHORITY
D/B/A JOHNSTON HEALTH
COMBINED STATEMENTS OF REVENUES, EXPENSES AND CHANGES IN NET ASSETS
YEARS ENDED SEPTEMBER 30, 2009 AND 2008**

	2009	2008
OPERATING REVENUE		
Net Patient Service Revenue (Net of Provision for Uncollectible Accounts of Approximately \$33,477,000 in 2009 and \$26,590,000 in 2008)	\$ 122,609,265	\$ 127,184,510
Other Operating Revenue	3,204,251	3,844,962
Total Operating Revenue	125,813,516	131,029,472
OPERATING EXPENSES		
Salaries, Wages and Contract Labor	59,618,145	57,935,894
Benefits	15,864,875	14,425,138
Fees - Medical	1,940,293	2,655,962
Fees - Other	10,014,042	9,590,310
Supplies	24,339,234	24,177,763
Utilities	3,234,706	2,894,377
Repairs and Maintenance	2,981,258	2,835,002
Leases and Rentals	2,447,837	2,343,994
Insurance	1,560,648	1,581,623
Other Expenses	1,276,501	1,590,067
Depreciation and Amortization	5,710,827	5,065,665
Total Operating Expenses	128,988,366	125,095,795
OPERATING INCOME (LOSS)	(3,174,850)	5,933,677
NON-OPERATING INCOME (EXPENSE)		
Interest Expense	(1,750,800)	(244,033)
Other Non-Operating Revenue, Net	245,787	1,475,989
Net Non-Operating Revenue	(1,505,013)	1,231,956
EXCESS OF REVENUES OVER (UNDER) EXPENSES, BEFORE CAPITAL GRANTS AND CONTRIBUTIONS	(4,679,863)	7,165,633
CAPITAL GRANTS AND CONTRIBUTIONS	1,432,308	-
INCREASE (DECREASE) IN NET ASSETS	(3,247,555)	7,165,633
Net Assets - Beginning of Year	89,074,252	81,908,619
NET ASSETS - END OF YEAR	\$ 85,826,697	\$ 89,074,252

See accompanying Notes to Combined Financial Statements.

Attachment 2



DIAGNOSTIC IMAGING, INC.

DIAGNOSTIC RADIOLOGY

ROBERT A. CERWIN, M.D.
ROBERT E. SCHAAF, M.D.
RICHARD J. MAX, M.D.
BRYAN M. PETERS, M.D.
CHARLES V. POPE, M.D.
ALAN B. FEIN, M.D.
DAVID LING, M.D.
CLAIRE M. POYET, M.D.
WILLIAM T. DJANG, M.D.
HOLLY J. BURCE, M.D.
JOHN SIERRA, M.D.
MICHAEL L. ROSS, M.D.
ANDREW C. WU, M.D.
WILLIAM G. WAY, M.D.
DENNIS M. O'DONNELL, M.D.
KAREN A. COATES, M.D.
DAVID F. MERTEN, M.D.
J. MARK SPARGO, M.D.
SISAN L. KENNEDY, M.D.
JOSEPH W. MELAMED, M.D.
C. GLENN COATES, M.D.
ELIZABETH A. RUSH, M.D.
JOHN MATZKO, M.D.
KERRY E. CHANDLER, M.D.
CARROLL C. OVERTON, M.D.
WILLIAM J. VANARTHOS, M.D.
LYNDON K. JORDAN, III, M.D.
JOSEPH B. CORNETT, M.D.
PHILIP C. PREITER, M.D.
M. RANS DOUGLAS, M.D.
MARGARET R. DOUGLAS, M.D.
JIMIE GAAL, JR., M.D.
RANDY D. SECRIST, M.D.
THOMAS L. PFEFFER, JR., M.D.
PHILIP R. SABA, M.D.
STEVEN R. MILLS, M.D.
R. DAVID MINTZ, M.D.
CYNTHIA I. CASKEY, M.D.
MICHAEL D. KWONG, M.D.
MELISSA C. LIPTON, M.D.
LOUIS F. POSILKO, M.D.
DUNCAN P. RUCKER-CHAFFMAN, M.D.
PAUL A. HAWKIN, M.D.
CARAFIO GULIOTTO, M.D.
RICHARD E. BIRD, M.D.
RUSSEL C. WILSON, M.D.
EITHNE T. BURKE, M.D.
SUSAN M. WEEKS, M.D.
PETER L. LEUCHEMANN, M.D.
TIMOTHY J. MIHALOVICH, M.D.
NIKUNI P. WASUDEW, M.D.

RADIATION ONCOLOGY

ANDREW S. KENNEDY, M.D.
SCOTT L. SAILER, M.D.
WILLIAM A. DEZARN, Ph.D., DABR

ADMINISTRATOR

W. H. JOHNSON

BUSINESS MANAGER

B. V. HILL

December 31, 2008

Ms. Lee B. Hoffman, Chief
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

Received by the
CON Section

31 DEC 2008 02 3:46

Dear Ms. Hoffman:

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Wake Radiology submits the attached comments related to the following application to develop a mobile MRI scanner in Wake and Johnston counties:

- Pinnacle Health Services d/b/a Raleigh Radiology at Cedarhurst ("Pinnacle"), Project ID # J-8268-08

The comments include "discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards" [NCGS 131E-185(a1)(1)(c)]. In addition to providing multiple bases for the application's non-conformity with relevant statutory and regulatory criteria, the comments also contain substantive reasons that the proposed project will not be beneficial to patients and should not be approved.

Thank you for considering these comments.

Sincerely,

Robert E. Schaaf, M.D.
President

GENERAL COMMENTS

Applicant

It is important to note that the applicant for the proposed project, Pinnacle Health Services ("Pinnacle"), only does business as "Raleigh Radiology at Cedarhurst," and is not a radiology group or a physician practice of any kind. While Section I of the application does not identify the applicant as a physician group, the use of the name "Raleigh Radiology" may lead to confusion with the radiology group of the same name, which does contract with Pinnacle for radiology interpretation services. This confusion is also present in the public hearing notice for the proposed project, which is entitled "Raleigh Radiology proposes mobile MRI scanner for Wake, Johnston counties." The impact of this distinction is explained in detail below, but the Agency should note that the applicant is not a physician group.

Recent Changes in CMS Regulations

Under the 2009 Medicare Physician Fee Schedule (MPFS), which is effective January 1, 2009, an entity furnishing mobile diagnostic testing services to Medicare beneficiaries must independently enroll in Medicare as an Independent Diagnostic Testing Facility (IDTF) and bill Medicare directly for the services it furnishes, regardless of where the services are furnished. This new enrollment and billing requirement applies to entities that furnish diagnostic testing services and thus would apply to Pinnacle's proposed mobile MRI scanner as well. According to federal regulations, specifically, 42 CFR 410.32 and 410.33, an IDTF must include a minimum level of physician supervision. Under Centers for Medicare and Medicaid Services (CMS) regulations governing reimbursement, "general supervision," which does not require a physician to be on site, is acceptable for non-contrast MRI procedures. However, MRI scans involving contrast require "direct supervision," which indicates that the supervising physician is actually in the same building as the MRI scanner during the entire procedure. While Pinnacle provides a letter from its proposed Medical Director, it does not state that he will be on site at each of the mobile sites Pinnacle proposes, particularly at those it projects to provide contrast procedures. Pinnacle does not currently provide full-time physician supervision at its Clayton and Wake Forest sites, and it does not state in the application that it will do so following development of this project. Without adequate physician supervision, Pinnacle would be unable to provide contrast MRI procedures to Medicare and Medicaid patients, which, aside from the financial implications, is also an ineffective alternative given the substantial number of providers in the service area that do have full-time, on-site physician coverage. While Pinnacle does not project any contrast procedures at Clayton, the CMS regulations would prevent it from performing any contrast studies on Medicare and Medicaid patients without physician supervision on site. In contrast, Wake Radiology has physician coverage at all its sites in the service area and will continue to do so.

COMMENTS RELATING TO STATUTORY REVIEW CRITERIA

- (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.*

This criterion requires applicants to demonstrate the need of the population to be served for the proposed project. Pinnacle does not show the need of its patient population for the mobile MRI scanner and therefore should be found non-conforming with this criterion. The following discussion details Pinnacle's non-conformity.

Unreasonable Utilization Projections

The application's projected utilization is based on unreasonable assumptions. Starting on page 56, the application presents its utilization methodology, which it repeatedly calls "conservative." In reality, the methodology is not as conservative as it is made to appear, as explained below.

1. Historical growth is for a short timeframe and therefore should not be used for determining the "conservative" nature of the projected utilization.

For each of its existing sites, including the fixed scanner at Cedarhurst and the mobile sites in Wake Forest and Clayton, Pinnacle has been operating only a short time. Thus, when comparing to its "historical" experience to state that its methodology is conservative, Pinnacle is relying on the start-up growth that is typically higher in the first few quarters and generally slows once the site has been established. Thus, comparing its projected growth rate to these historical start-up months' growth rates is invalid.

2. The actual growth rates are much higher than they appear.

Rather than projecting utilization based on total annual increases, the application projects growth based on scans per day. In addition, the application states its projected compound annual growth rate for only the project years. However, when examining both the compound annual growth rate (CAGR) from the last

historical year through the third project year, as well as the resulting total annual scan growth, the growth is much higher.

For the Wake Forest site (shown on page 57), utilization is projected to grow from 8.2 scans per day in CY 2008 to 9.5 scans per day in CY 2012, which is a CAGR of 3.7 percent. The total scan volume is projected to grow from 1,388 in CY 2008 to 1,976 in CY 2012, which is a CAGR of 9.2 percent. Much of this growth is projected to occur in CY 2009, the intervening year, which masks the project year growth. However, the applicant is still projecting its scan volume to increase by the CAGR of 9.2 percent.

For the Clayton site (shown on page 60), the utilization is similarly projected. The application presents the volume growth as conservative; however, the scans per day are projected to grow from 7.0 in CY 2008 to 9.5 in CY 2012, a CAGR of 7.9 percent, even higher than the Wake Forest site. The total scan volume is projected to grow from 668 to 988 in the same timeframe, a CAGR of 10.3 percent. Clearly, the utilization projections are not as conservative as the 2.7 percent shown in the application narrative.

The methodology for these two sites is in stark contrast to the utilization methodology for the Cedarhurst site (shown on page 62), for which the "scans per day" methodology is not used, but total annual volume is projected to grow 3.0 percent per year.

In order to examine the reasonableness of Pinnacle's projections, the total annual volume growth must be analyzed, since data for "scans per day" is not available publicly and cannot be used for comparison purposes. As stated above, Pinnacle projects growth in total scans per year for Wake Forest and Clayton to be 9.2 and 10.3 percent, respectively. These growth rates are considerably higher than the growth rates for Wake and Johnston counties as well as for North Carolina as a whole. On pages 54 and 55, Pinnacle states that the compound annual growth rate for Wake County's MRI use rate was 6.9 percent from 2004 to 2006; for Johnston County, the use rate growth was 4.0 percent for the same period. On page 58, Pinnacle states that the North Carolina MRI utilization rate has experienced a five-year CAGR of 7.3 percent and that Wake County has experienced a two-year CAGR of 6.9 percent. The following tables show the projected CAGR in total scans for the Wake Forest and Clayton sites, along with comparable historical data presented in the Pinnacle application.

Wake Forest Site

Wake Forest population growth*	5.5%
NC MRI growth rate*	7.3%
Wake County MRI growth rate*	6.9%
Pinnacle total MRI scan CAGR	9.2%

*Source: Pinnacle application, page 58

Clayton Site

Clayton population growth*	4.0%
NC MRI growth rate*	7.3%
Johnston County MRI growth rate*	4.0%
Pinnacle total MRI scan CAGR	10.3%

*Source: Pinnacle application, pages 60-61

As the tables show, using comparable statistics, the projected annual growth rate for both Wake Forest and Clayton are much higher than the other statistics presented in the Pinnacle application and are therefore unreasonable.

3. Sufficient MRI capacity exists in Wake and Johnston counties.

Although the projected volume growth at both the Wake Forest and Clayton sites are unreasonably high, the total volume projected for the new mobile MRI scanner is 3,567 weighted MRI procedures, as shown on page 63. Of this total, 988 procedures are projected for Johnston County and the remaining 2,579 for the two Wake County sites. The application does not show or even attempt to explain why existing providers cannot meet the need for these 3,567 procedures, particularly in light of existing capacity and other approved new MRI scanners. According to Table 9J on page 173 of the Proposed 2009 SMFP, Wake County has a total of 15.52 "fixed equivalent magnets" with an average of 4,280 procedures per MRI, compared to the threshold for an additional fixed MRI of 4,805. Thus, the total available capacity is approximately 8,148 weighted procedures ($4,805 - 4,280 = 525 \times 15.52 \text{ magnets} = 8,148$). Thus, Wake County providers currently have available capacity for the projected 2,579 Pinnacle procedures, assuming they are all "new" procedures in the county. Moreover, most of the available capacity is at sites in northern Wake County (near the proposed Wake Forest and Cedarhurst sites) or on mobile scanners, which provide care at multiple locations throughout the area. As shown in Table 9J, Rex Healthcare of Wakefield has a CON to develop a mobile

MRI site in Wakefield. According to Rex's website¹, the site is near downtown Wake Forest and will be opening in March 2009; thus, that CON-approved site will be available in the next few months for Wake Forest and northern Wake residents. As part of the Rex Healthcare system, that site will likely utilize Raleigh Radiology for interpretation of its MRI procedures; thus, Pinnacle, through its relationship with Raleigh Radiology, should be aware of this fact. Wake Radiology also has an existing office in Wake Forest and will begin offering mobile MRI services at that office at least two days per week beginning in early 2009, but will do so with an existing mobile MRI scanner and will not require the expense of a new mobile MRI scanner as Pinnacle is proposing.

In Johnston County, available capacity also exists. According to Table 9J on page 169 of the Proposed 2009 SMFP, Johnston County has 2.08 "fixed equivalent magnets" with an average MRI volume of 3,040 procedures, which is less than the 4,118 threshold needed to trigger need for an additional fixed magnet. Thus, the total available capacity in Johnston County is 2,242 ($4,118 - 3,040 = 1,078 \times 2.08 = 2,242$). Most critically, the approved MRI shown as the 2007 SMFP need determination was awarded to Johnston MRI, LLC for a fixed site in Clayton. Thus, a freestanding provider (from a reimbursement perspective) has already been approved for Clayton. Further, that CON-approved MRI scanner is still under development; therefore, the capacity of a full-time fixed MRI scanner will be available for residents of Clayton and the surrounding area. Pinnacle mentions the development of this MRI scanner in Clayton on page 59 of its application; however, it does not account for the presence of a full-time fixed MRI scanner in its projections. In fact, Pinnacle only states that it "does not anticipate a negative impact" and points to the growth in the Clayton community. However, as noted above, the growth in population and MRI utilization is lower than the annual MRI utilization growth projected by Pinnacle.

4. The projected utilization likely includes "shifted" volume.

As explained above, Pinnacle projects its utilization growth to be significantly higher than the historical MRI growth rate for Wake and Johnston counties or the state as a whole. As such, even if it were able to achieve its projected utilization, it would require shifting patients from other providers to Pinnacle. In other words, since MRI utilization has historically grown at a slower annual rate than the utilization growth projected by Pinnacle, any increase in

¹ http://www.rexhealth.com/services_and_wellness/hospitals_and_locations/wakefield.asp

utilization at Pinnacle above the growth in overall utilization in the service area is the result of volume shifting from other providers. Pinnacle does not show the need of its patients to have their MRI performed at Pinnacle versus another existing provider. Given the availability of MRI capacity in Wake and Johnston counties, particularly the new fixed MRI being developed in Clayton and the Rex mobile MRI site in Wakefield (with interpretation of MRI procedures being provided by Raleigh Radiology), the need to shift volume from other providers has not been demonstrated.

5. The physician support letters were solicited by Raleigh Radiology, not Pinnacle, and the letters may be intended to support the radiologists, not the applicant.

In its attempt to show need for the project, notwithstanding the high utilization growth rates and other unreasonable assumptions, Pinnacle refers repeatedly to its physician support letters. These letters, however, do not refer to Pinnacle, the applicant, but to Raleigh Radiology Cedarhurst. While this difference may seem immaterial, given the use of the name "Raleigh Radiology," which is a well-known and respected radiology group in its own right, it is likely that at least some physicians intended to support Raleigh Radiology, not Pinnacle. The letters sent by Pinnacle to solicit support from physicians also contribute to the confusion. As shown in Attachment 1, the letters sent to local physicians were not on Pinnacle letterhead, but on the letterhead of Raleigh Radiology, the physician group. The fact that this letterhead is for the physician group and not Pinnacle is confirmed by examining the letterhead used by the Medical Director in Exhibit 4 on page 226. This letter is from a Raleigh Radiology physician and is on the same letterhead as that used to solicit support for Pinnacle's project. As noted at the start of these comments, Raleigh Radiology provides interpretation of the MRI procedures for Pinnacle, but is not an applicant in this review. By sending the support letter solicitation on Raleigh Radiology letterhead, it is likely that a number of physicians believed they were supporting Raleigh Radiology, not Pinnacle.

6. CMS regulations will restrict Pinnacle's ability to perform contrast studies.

As explained on the first page of these comments, recent changes to the CMS regulations for IDTF's require full-time physician coverage for sites that perform contrast studies. Pinnacle fails to demonstrate that it will have a physician on site in order to perform contrast studies to Medicare and Medicaid patients. The application does not account for this factor in the utilization

assumptions; therefore the assumptions are incorrect, particularly regarding contrast and Medicare/Medicaid patients.

Overall Need

Wake Radiology believes it is important to consider the overall need (or lack thereof) for additional MRI equipment in the service area. The Pinnacle application states several times that the proposed project will be beneficial from a cost perspective; however, the application is not referring to costs to patients or the health care system, but to its own operating costs. Reimbursement from payors is not based on whether the MRI equipment is leased from a vendor or owned by the provider; thus, the application does not show how costs to the health care system will be lowered through the proposed project. Given the current economic climate, it is imperative to consider whether additional diagnostic equipment is needed in the area, particularly with the \$2.3 million in capital costs proposed by the applicant.

Since 2005, approximately 12 CON applications for new mobile MRI scanners have been reviewed; of these, fewer than half were approved, indicating that the CON Section has been finding little need for additional mobile MRI capacity. One of these applications, J-7442-05, proposed a mobile MRI scanner to “replace” existing mobile MRI capacity with another mobile MRI, similar to the proposed Pinnacle project. Pinnacle indicates that the proposed new mobile MRI will be used to replace the capacity of the scanner provided through a contract with Alliance Imaging (page 67). Thus, the Alliance Imaging scanner, which is likely one of its many “grandfathered” mobile MRI scanners, which are not subject to CON regulations, will be available to relocate elsewhere. However, Pinnacle has not indicated where Alliance will relocate the scanner or what need there is for that scanner elsewhere. In the findings for the project noted above, J-7442-05, the Agency found the application non-conforming with Criterion 3, stating on pages 4 and 5,

“Therefore, it appears that the acquisition of new equipment to provide services already provided with existing equipment has the net effect of allowing Alliance to move existing equipment to new locations without an analysis of the need for mobile MRI services at those locations. However, the applicants do not identify the other host sites where the existing mobile MRI scanners, which currently serve Burlington, Durham and Wallace, will be utilized. Consequently, the applicants do not document that additional days of service are needed at the sites where the equipment will be moved. Thus, the applicants do not demonstrate the need for the

expansion of MRI service capacity to the other unidentified sites that will result from the addition of the proposed new MRI scanner.”

Similarly, the Pinnacle application has the net effect of allowing Alliance to move its mobile MRI scanner without any analysis of the need for services at those locations. Pinnacle proposes to expand the overall mobile MRI capacity without documenting the need to do so.

Although the application cites various benefits of the new mobile MRI scanner, it does not explain the need for these benefits by the patient population to be served that cannot be met by existing providers or by Pinnacle's existing fixed MRI scanner. On page 19, the application states that the proposed mobile MRI scanner, which will replace an existing vendor-provided mobile MRI scanner, will reduce the cost of providing the service. However, the application does not show if or how this lower cost will benefit Pinnacle's patients. In fact, given that there is no demonstrated need for additional MRI capacity in the service area (discussed above), the lower cost for the health care system would be to keep the existing mobile MRI contract, which results in no additional capital cost. It is important to note that the Wake Forest and Clayton sites were developed through the use of a mobile MRI vendor that is not subject to CON constraints. As such, Pinnacle has never had to demonstrate need to offer mobile MRI services at these sites, and given the CON-approved mobile and fixed MRI capacity soon to be available in these areas, Pinnacle should not be given any presumptive credit for the patient need at these sites, which can easily be met by these other CON-approved projects under development.

On page 20, the application refers to the need for control over its mobile MRI scanner, including such issues as the types of coils available, staffing, scheduling and long-term availability. However, the application does not show how these issues negatively impact patients and why the new mobile MRI scanner is needed by the patient population because of these issues. First, regarding the coils, specifically the breast coils: breast MR imaging, while beneficial to a select group of patients, is a low volume procedure and is already provided by other providers in the service area, including Rex Hospital (with MRI interpretation provided by Raleigh Radiology), which reported performing 222 breast MR procedures in FY 2007, which was less than two percent of the total MRI procedures it performed that year². Wake Radiology also offers breast MRI at its Raleigh MRI Center (as well as at its Chapel Hill office) and has performed approximately 759 breast MRI procedures to date in 2008. Pinnacle itself owns a fixed MRI scanner in north Raleigh which it should be able to use for any breast procedures needed by its patients. As shown on page 239 of Exhibit 6, however, Pinnacle does not even provide breast MRI on the existing fixed scanner that it owns and controls; therefore, the need for it at the lower

²

Data from Rex Hospital License Renewal Application for 2008.

volume mobile sites is unsupported. Further, the application does not document how Pinnacle accounted for the additional volume of breast procedures that it would be able to perform with the new mobile MRI scanner; thus, it did not demonstrate the need for the breast coils that is not currently being met. As an existing provider, it should have records of the number of patients that need this service and how a lack of these coils impacts the patients, if at all.

The remaining issues of staffing, scheduling and long-term availability may be operational issues for Pinnacle, but given the availability of MRI capacity in the service area (discussed above), the application does not demonstrate why these issues result in a patient need.

On page 21, the application discusses the need for improved access through the proposed project, referring to its proposed scanner as an "open MRI." However, the open bore design is not a true "open" scanner; rather, the design, which is typical of modern units, has a large opening compared to earlier MRI scanners with narrow bores. Further, the applicant states that the proposed magnet "can accommodate more types of patients than other 1.5T systems on the market today..." (page 21); however, the proposed Siemens Open Bore magnet is the same magnet proposed by Johnston MRI, LLC to be located in Clayton, according to Section II.1, page 13 of the Johnston MRI application. Unlike the Pinnacle magnet, the Johnston MRI, LLC scanner will not be located inside a mobile trailer, which in itself can be a barrier to access for obese or claustrophobic patients. As an existing provider, Pinnacle could have provided the number of obese or claustrophobic patients that cannot be scanned on its existing mobile MRI unit; however, it failed to provide such evidence of need.

The application also refers to a wait time of three to five days for an MRI scan (page 22); however, given the available MRI capacity in Wake and Johnston counties discussed above, it is unclear why Pinnacle has not informed its patients that other MRI scanners have available capacity to serve them. In addition, the application projects Pinnacle's MRI volume to continue to increase in the intervening timeframe; thus, it appears that Pinnacle has available capacity for this increased volume, but is not utilizing it effectively to reduce wait times for its current patients.

- (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.*

Pinnacle fails to demonstrate that the proposed new mobile MRI scanner will meet the needs of its patients that the vendor-provided mobile MRI service cannot provide. In particular, the application does not show that

the proposed mobile MRI scanner will result in lower costs compared to the existing service. As discussed under Criterion 3, the applicant proposes a \$2.3 million scanner to essentially replace what would exist through the vendor if there were no capital expenditure and does not show why maintaining the status quo is not a more effective alternative, given the available capacity in the service area.

- (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.*

In addition to providing unreasonable utilization methodology assumptions, Pinnacle also provides insufficient financial information and should be found non-conforming with this criterion on that basis.

Section X of the CON application form asks applicants to provide Form B, which is a statement of revenues and expenses for the entire facility. The application states on page 123 that "Form B and Form C are the same because PHS is proposing to acquire a mobile MRI scanner, which performs only MRI scans. Therefore, no Form C is included in Section XIII." However, Form C requests information for the proposed service component (mobile MRI) and Form B is for the entire facility. However, Pinnacle provides Form B for the mobile MRI service only, not the entire facility as required, including the MRI procedures projected for the fixed MRI at Cedarhurst, as well as revenue for other services provided by Pinnacle. Exhibit 13 contains the compiled financials for Pinnacle, which show on page 323 that the facility had more than \$19 million in gross revenue in 2007; however, no pro forma information is provided in the Pinnacle application for the facility.

Section X also requests information for the last fiscal year and the intervening years prior to operation of the proposed project. However, Pinnacle has provided information for only the three project years. Since the applicant currently provides MRI services using a mobile MRI service and projects to continue doing so until development of its proposed new mobile MRI, information for the last fiscal year and pro formas for the intervening timeframe should be available. This information is particularly necessary, given the application's discussion of the need to lower the cost of providing the existing vendor-owned MRI service. Without this information, the application does not demonstrate that the proposed project will result in lower costs, particularly for patients.

As explained under the general comments above, Pinnacle fails to demonstrate that it will have sufficient physician coverage to meet CMS

requirements for Medicare and Medicaid contrast scans. Thus, its projected reimbursement for these procedures is in question and its projected revenue is overstated given that failure to satisfy the conditions of IDTF-reimbursement could result in the denial of claims for diagnostic testing services or a revocation of billing privileges.

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

As discussed under Criterion 3, the CON Section has approved the development of additional MRI scanners in the service area. Specifically, Johnston MRI, LLC has been approved to develop a fixed MRI scanner in Clayton, one of the sites proposed by Pinnacle, and Rex Healthcare has been approved to develop mobile MRI services in Wakefield, near Wake Forest. Neither of these CON-approved providers is yet operational; therefore, each will provide capacity in areas proposed to be served by Pinnacle. However, Pinnacle does not provide any analysis of the capacity represented by these approved providers nor how this capacity will affect its proposed project. Given this capacity and Pinnacle's failure to include it in its need analysis, Pinnacle has failed to demonstrate that it will not unnecessarily duplicate the existing and approved health service facilities in the service area.

COMMENTS RELATING TO CRITERIA AND STANDARDS FOR MRI SCANNERS

10A NCAC 14C .2704(a)

The applicant refers to the availability of its fixed site at Raleigh Radiology Cedarhurst when the mobile MRI is unavailable. The application does not provide the population to be served by the Clayton site; however, it is reasonable to assume that most of the projected Johnston County patients would be served at this site. The Cedarhurst site is in northern Wake County and is not in proximity to Johnston County; thus, the applicant does not show that it has a referral arrangement with another provider in the geographic area. Given the approval of the Johnston MRI, LLC fixed MRI scanner in Clayton as well as numerous other fixed MRI scanners closer to Clayton than the Cedarhurst site, the application should include an agreement with a closer site. Referring a patient from Clayton to Cedarhurst is clearly unreasonable and does not meet the requirement of this rule.

Attachment 1

Raleigh Radiology
Blue Ridge
3200 Blue Ridge Road,
Ste 100
Raleigh, NC 27612
T 919-781-1437
F 919-787-4870

Raleigh Radiology
Cedarhurst
1212 Cedarhurst Drive
Raleigh, NC 27609
T 919-877-5400
F 919-877-5480

Raleigh Radiology
Cary
251 Kessler Drive
Ste 100
Cary, NC 27518
T 919-781-1437
F 919-787-4870

Raleigh Radiology
Brent Center
3900 Barrell Drive
Ste 100
Raleigh, NC 27608
T 919-781-1437
F 919-787-4870

Raleigh Radiology
Clayton
300 Guy Road
Ste 102
Clayton, NC 27520
T 919-877-5400
F 919-877-5480

Raleigh Radiology
Wake Forest
638 Durham Road
UdVA
Wake Forest, NC 27587
T 919-877-5400
F 919-877-5480

Raleigh Radiology
at Rex Hospital
1420 Lake Boone Trail
Raleigh, NC 27607
T 919-784-3419
F 919-784-3497

September 2, 2008

Dear Physicians and Staff,

Thank you for your continuing support. In the efforts to continue to expand and improve our MRI services for physicians and patients, Raleigh Radiology Cedarhurst is submitting an application for a **Certificate of Need (CON)** to acquire and operate a mobile MRI scanner at host sites in Wake and Johnston counties.

We currently have exceptional MRI services in Wake Forest, Clayton and Cedarhurst 7 days per week. The services in Wake Forest, Clayton and some incremental days at Cedarhurst are through a third party; however, we look forward to improving patient access to mobile MRI services by expanding the MRI availability and reducing costs associated with providing the service. We would greatly appreciate your support for CON approval. We know the approval of the CON will result in improved service to you and your patients. Enclosed you will find support letters for signatures and a stamped return envelope to Raleigh Radiology Cedarhurst for your convenience. The included annual referral projections are based on your referral history to the above sites. Thank you for your support.

Sincerely,



W. Kent Davis, MD
Medical Director

Ms. Lee Hoffman
N.C. Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Center Service
Raleigh, NC 27699-2704

Dear Ms. Hoffman,

As a physician who refers patients for Magnetic Resonance Imaging (MRI) exams, I am writing this letter to indicate my support for the Certificate of Need application filed by Raleigh Radiology Cedarhurst (RRC) to acquire and operate a mobile MRI scanner at three host sites in Wake and Johnston counties.

RRC and Raleigh Radiology have a strong reputation for delivering quality services and superior diagnostic work. In recent years, MRI utilization at RRC has dramatically increased. In fact, the current demand is such that some of my patients currently must wait several days to schedule an appointment.

High quality MRI images are very helpful in providing my patients with an accurate diagnosis. Many of my patients utilize the RRC imaging centers in Wake and Johnston counties. RRC seeks to improve upon the services currently being offered at these sites by purchasing a mobile MRI scanner. In doing so, RRC will improve access to mobile MRI services by expanding mobile MRI availability and reducing the costs associated with providing the service. This will undoubtedly lead to improved, convenient, and timelier access for my patients. The majority of diagnostic imaging patients are outpatients, thus, RRC's proposal to acquire and operate a mobile MRI scanner at Wake Forest and Clayton, and to supplement the busy fixed MRI scanner at the Cedarhurst facility, is logical and will be of great benefit to the local community. In addition, the open design of the proposed mobile MRI scanner will better enable the host imaging centers to accommodate obese and claustrophobic patients.

If RRC's application is approved and based on my recent MR referrals to RRC, I anticipate I will refer approximately 2 patients per year to RRC MR Services.

Sincerely,

(Signature)

(Print Name)