



DukeMedicine

Duke University Health System by the
CON Section

Duncan Yaggy, Ph.D.
Chief Planning Officer

02 AUG 2010 3:06

July 30, 2010

Michael J. McKillip, Project Analyst
Division of Health Service Regulation
Certificate of Need Section
2704 Mail Service Center
Raleigh, NC 27699-2704

Re: Project ID# J-8534-10 and Project ID# J-8537-10

Dear Mr. McKillip:

This letter forwards the comments of Duke University Health System on Project ID# J-8534-10 and Project ID# J-8537-10.

If you have questions about them, please let me know.

Sincerely,

Duncan Yaggy, Ph.D.
Chief Planning Officer
Duke University Health System

02 AUG 2010 3 : 06

Comments on the Application of Wake Radiology for a Fixed MRI Scanner

Project ID# J-8534-10

Submitted by Duke University Health System d/b/a Duke Raleigh Hospital

Wake Radiology has proposed to acquire a fixed MRI scanner and install it in a medical office building in Garner. This application is nonconforming with the applicable criteria and should be disapproved.

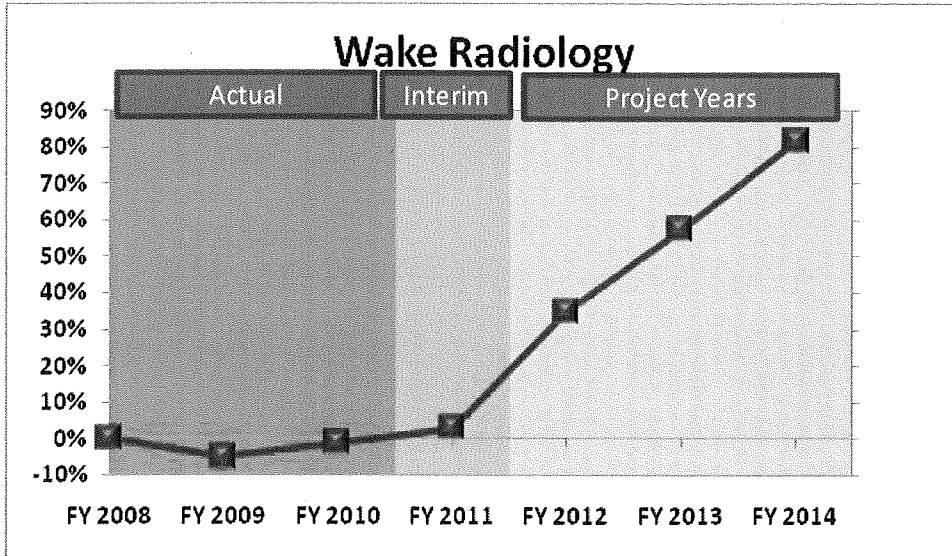
Utilization Projections

The central problem with the Wake Radiology application is illustrated in the following table, which reproduces volumes, actual and projected, appearing on pages 99 and 100 of the application, which we utilized to calculate the year to year change in volume:

	Wake Radiology Weighted Procedure	% Change from Previous Year	
FY2008 (Actual)	2,723		} 2.75%
FY2009 (Actual)	2,585	- 5.1%	
FY2010 (Projected) – Interim	2,690	+ 4.1%	
FY2011 (Projected) – Interim	2,798	+ 4.0%	} 76.7%
FY2012 (Projected) – Project	3,670	+ 31.2%	
FY2013 (Projected) – Project	4,285	+ 16.8%	
FY2014 (Projected) – Project	4,945	+ 15.4%	

The graph on the following page illustrates Wake Radiology's projections. Between 2008 and 2011 the number of weighted procedures provided by the mobile at Garner will increase by a total of 2.75%, from 2,723 procedures in 2008 to 2,798 procedures in 2011. Then the fixed is installed, and the volume suddenly explodes. Between 2011 and 2014 the number of weighted procedures is projected to increase 76.7%, from 2,798 procedures in 2011 to 4,945 procedures in 2014.

Cumulative Growth of Weighted MRI Procedures from FY 2008 to FY 2014



This projection enables the application to meet the CON requirement that the proposed fixed MRI scanner provide at least 4,805 weighted procedures during its third year of operation. It also helps to reduce the projected cost per procedure.

But where will all these patients come from?

By way of response, Wake Radiology submits letter promising referrals from 175 local physicians. Presumably, these physicians are already referring patients to Wake Radiology for MRI scans, and will continue to refer in similar patterns. Will their referrals for MRI procedures increase 76.7% between 2011 and 2014? If not, where will the additional patients come from?

What about other Wake Radiology MRI sites? They could be a source of referrals for Garner, except for the fact that Wake Radiology will use the mobile MRI now serving Garner to increase the number of machine days at other Wake Radiology sites. In short, referrals from other Wake Radiology offices to Garner are likely to go down, not up.

Where will all the additional patients come from? The application is reduced to projecting:

- Continued growth of MRI volume in Wake County, at the rate of 4% per year as calculated by Wake Radiology. If that growth were achieved, despite growing constraints on the reimbursement of MRI procedures, and the Garner machine maintains its share, the utilization of the Garner machine would grow by about 500 unweighted scans annually by 2014.

- A dramatic increase in market share for the Garner machine – from 3.2% in 2009 to 4.0% in 2013 to 5% in 2014. That’s a volume increase of 56% in 5 years. Where will that increase come from? The application does not provide that information.
- The application also projects that 34% of patients will come from Johnston County, yet provides no support for this source of volumes, either in projected population growth in that county or projected market share. This is problematic, especially in light of Johnston MRI, LLC’s newly installed fixed MRI in Clayton, located less than 9 miles from the Garner project location. According to the proposed 2011 State Medical Facilities Plan, the fixed MRI scanner in Clayton only performed 47 weighted scans in the short time it has been open during FY 2009.

Section 10A NCAC 14C .2703 (b) (3) requires applicants for fixed MRI scanners to “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 and REASONABLY EXPECTED to perform the following number of weighted MRI procedures...(E) 4805 weighted MRI procedures in MRI service areas in which the State Medical Facilities Plan shows four or more fixed MRI scanners are located”.

We believe that the fixed MRI that Wake Radiology has proposed cannot be REASONABLY EXPECTED to provide 4,945, 4,805 or even 4,000 weighted procedures in the third year following completion of the project.

02 AUG 2010 3 : 06

Comments on the Application of North State Imaging, LLC for a Fixed MRI Scanner

Project ID# J-8537-10

Submitted by Duke University Health System d/b/a Duke Raleigh Hospital

North State Imaging, LLC d/b/a NCDI – Holly Springs has proposed to acquire a fixed MRI scanner and install it in a medical office building in Holly Springs. The parent company of North State Imaging, LLC is Novant Health; the facility will be managed and operated by MedQuest Associates, Inc. The applicant will be referred to as Novant in these comments.

Failure to Support Utilization Projections

The fundamental problem with Novant's application is the failure to document or support its extraordinarily aggressive utilization projections.

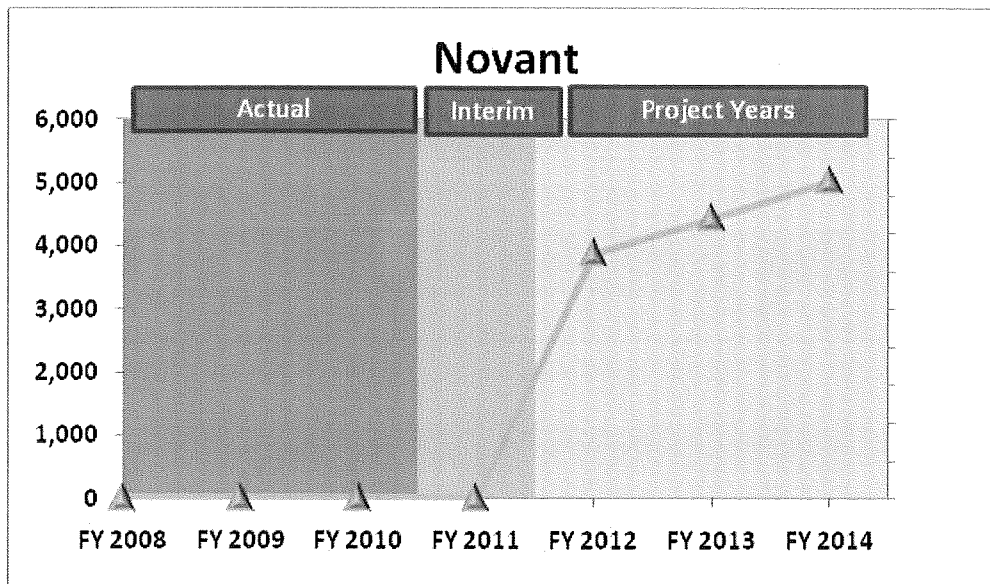
The key driver of Novant's projected volume is an assumed market share within the primary service area. Novant assumes immediate and rapid growth in market share upon completion of the project, as high as 50% market share in the first year within one census tract. Novant does not provide adequate documentation of its ability to attain these market share values. Letters of support from only 14 physicians were included in the application. Of these letters, 10 physicians (from 2 practices) project their referral volume which totals 117 scans in year 1 (3.25% of total year 1 volume), and the remaining did not project any specific number of scans. Moreover, none of these providers are currently based in Holly Springs, but instead in Wake Forest and Cary. In fact, the applicant acknowledges the lack of current referral relationships by stating, on page 14, "*NCDI will build physician relationships with a number of local providers through its marketing efforts and the provision of quality care.*" It has not provided, however, a plan of how it will build the relationships necessary to generate the other 3,483 unweighted scans required to reach the 3,600 projected for year one of the project.

Novant states on page 63 that "*The Novant Medical Group of general surgeons is exploring a satellite office location in Holly Springs.*" (emphasis added). Since this same statement was included in the Novant application for the Holly Springs Surgical Center, we conclude that there is no reason to assume that a satellite office will be developed or that it will refer a substantial number of patients to the proposed fixed scanner.

Novant tries to make the weakness of its application a strength by arguing, on page 14, that "*NCDI is a unique applicant in that it does not have exclusive agreements with specific physicians groups and will receive referrals from both local and regional physicians. NCDI will build physician relationships with a number of local providers through its marketing efforts and*

the provision of quality care.” Because it will not have any exclusive agreements, it must rely on referrals from physician groups that have, and will continue to have, referral patterns to other providers. It is also important, therefore, to determine the potential volumes that these non-exclusive relationships will generate if and when they are ever developed. As it currently stands, Novant has an extremely limited number of non-exclusive relationships with physician groups, projected to generate only a small percentage of the number of scans necessary to support a new MRI in Holly Springs.

Growth of Weighted MRI Procedures from FY 2008 to FY 2014



With physicians supporting the project collectively projecting less than 120 MRI referrals annually, the likelihood of reaching 3,600 unweighted scans in year 1, and 4,661 unweighted scans by year 3, is remote. Half those totals would be more likely, but inadequate to a demonstration of financial feasibility. Based on stated gross and net patient revenue, the breakeven volume in the first year is 2,638 scans (growing to 3,162 scans by Year 3). If Novant is only able to achieve 50% of its projected volume in year 1, the gross patient revenue would have increase to \$4,092 per unweighted scan to maintain financial feasibility. Both the utilization and the financial feasibility of this project are therefore in doubt.

Financial Methodology

In order to promote cost-effective approaches, as stated in page 73, the same charges will be maintained for each of the three project years. By ignoring inflation effects, Novant can project lower costs and revenue per scan than the other applicants.

Additionally, on page 66, Novant set the contrast percentage at 19.5% for a fixed MRI scanner, which is based on its experience with the **mobile** MRI scanner in Cary, which performed 388 total scans. This ratio is determined to be reasonable given “the experience of existing fixed

MRI providers in Wake County.” However, at the other outpatient fixed MRI facilities in Wake County, the contrast ratio ranges from 22.6% to 45.3%. The low percentage of contrast scans allows Novant to project lower costs, lower patient revenues, and lower charges due to the lack of utilization of contrast material.

Failure to Consider Appropriate Alternatives

In light of the low volumes actually projected by the physicians supporting this application, Novant should have considered more appropriate alternatives. One alternative apparently not considered by the applicant was the substitution of a fixed MRI for the mobile MRI at their Cary facility, where Novant currently has an established location, practice, and referral relationships. As stated on Page 75, “*mobile MRI service has its limitations*” such as the cost of services, limited accessibility, and technological disadvantages.

Mobile MRI service was rejected as an alternative because of the limitations of mobile MRIs and a fixed MRI “*would be more beneficial to the growing population base in southern Wake County.*” However, entering a market with no established referral patterns or patient base, it would be more prudent to contract with a mobile provider to begin offering services in the market to grow patient volumes. Although the cost of a mobile may be more expensive, it will be more cost-effective in the likely scenario that Novant is unable to reach 3,600 scans within the first year.

Staffing

Novant states that while 2.5 Radiology Technologists will be hired for the Holly Springs facility, radiologists at Durham Radiology will provide professional interpretation services for the MRI scans conducted at NCDI-Holly Springs. Information is not provided indicating that the current physicians have either the capacity to interpret 3,600+ more MRI scans or plans to recruit an additional radiologist at Durham Radiology.

Access to Services for Underserved Groups

The applicant states on page 73 that “if its CON application is approved, NCDI-Holly Springs will work with Project Access in Wake County to develop a partnership to provide access to the proposed fixed MRI scanner for those individuals with limited or no financial resources....If NCDI-Holly Springs is approved, it will work with Project Access to provide approximately 100 to 150 free MRI procedures annually to area residents.” (emphasis added) While a letter from Novant to Project Access was provided, dated June 4th, no evidence of a partnership or agreement was provided to verify the number of scans committed or needed.

Novant estimates that 8.1% of the MRI scans will be self-pay, indigent, and charity care patients. In year 1, that equates to 293 scans, 202 of which will be charity care, including Project Access. Novant states that “it is assumed that Indigent and Charity patients will pay \$0.” Thus, the remaining 71 self-pay patients are expected to provide \$63,944 in net reimbursement per Form E, equating to an average reimbursement of \$900.62. Does Novant expect its self-pay patients to pay at 117% the rate of Commercial and Managed Care insurers?

Additionally, Novant does not provide adequate justification for its assumption of 8.1% self-pay, other than to state “percentage allocation for each payor is based on historical payor mix for MedQuest sites in the region.” However, the region is not defined and the experience within Wake County as a whole is likely quite different than the Holly Springs region. In fact, the zip codes from which the bulk of the projected patients are originating has a significantly more attractive payor mix than the Wake County population as a whole. Per Thomson Reuters, only 6.7% of the population within zip codes 27539 and 27540 (Holly Springs) are uninsured, as compared to 12.3% of Wake County as a whole.

Other Concerns

Over the past two weeks, several news articles have raised concerns regarding Novant’s financial situation and its willingness and ability to complete projects and to maintain the services of existing facilities.

- Waterford Diagnostic Imaging, a North Carolina Diagnostic Imaging / MedQuest facility, in Leland closed in mid-July.¹
- Cape Fear OB/GYN in Wilmington is scheduled to close on August 2nd.²
- Novant Health eliminated 48 jobs in Winston-Salem at Forsyth Medical Center and Medical Park Hospital in addition to 18 jobs at Brunswick Community Hospital. The stated reason for the layoffs was the need to cut costs as a result of high unemployment rates, low Medicaid reimbursement rates, patients losing health insurance, and patients postponing elective surgeries and regular exams.^{3,4}
- The opening of the Kernersville Medical Center, previously slated to open Spring of 2010, has been pushed to the third quarter of next year, and “even that may come under review.”⁵

This stated in light of their continued argument of having a great charity care program and providing care for high rates of self-pay and Medicaid patients, raising the question, if the Holly Springs facility does not achieve expected volumes, reimbursement, payor mix, and financial feasibility, will Novant also shut down this service?

¹ NC Diagnostic Imaging closes in Leland, patients must go to Wilmington. *WECT News 6*. July 29, 2010.
<http://www.wect.com/global/story.asp?s=12831996>

² Cape Fear OB/GYN to close in August. *WECT News 6*. May 28, 2010.
<http://www.wect.com/Global/story.asp?S=12562524>

³ Novant will cut 48 jobs in Winston-Salem. *The Triad Business Journal*. July 13, 2010.
<http://triad.bizjournals.com/triad/stories/2010/07/12/daily16.html>

⁴ Brunswick Community Hospital eliminates 18 positions. *The Brunswick Beacon*. July 13, 2010.
<http://www.brunswickbeacon.com/content/brunswick-community-hospital-eliminates-18-positions>

⁵ Kernersville Medical Center opening might be further delay. *The Triad Business Journal*. July 31, 2009.
<http://www.bizjournals.com/triad/stories/2009/08/03/story9.html>