

August 27, 2010

Mr. Craig Smith, Chief  
Certificate of Need Section  
Division of Health Service Regulation  
2704 Mail Service Center  
Raleigh, NC 27899-2704

RE: Comments regarding CON Project ID # G-8554-10, Excel Imaging, LLC d/b/a Forsyth  
Medical Center Imaging-Clemmons

Dear Mr. Smith:

On behalf of Alliance Healthcare Services, thank you for the opportunity to comment on the above-referenced project application. These comments are submitted in accordance with NCGS 131E-185(a1)(1) and reference specific statutory criteria and special demonstration project criteria and rules relevant to this review.

Thank you for your consideration of the enclosed information. Should you have any questions, please do not hesitate to contact me.

Sincerely,



David J. French  
Consultant to Alliance Healthcare Services

In CON Project ID # G-8554-10, Excel Imaging, LLC d/b/a Forsyth Medical Center Imaging-Clemmons (parent company Novant Health, Inc.) proposes to obtain a fixed GE 1.5 T 450W open MRI scanner to be installed at Novant's FMCI-Clemmons location. FMCI-Clemmons would be staffed by Triangle Radiology Associates, PLLC.

The CON application is non-conforming to specific CON review criteria and MRI regulatory standards as described in the paragraphs below

*CON 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.*

In November of 2007, Novant Health, Inc. was issued a CON, #G-7919-07, for the addition of one fixed MRI scanner at their Forsyth Medical Center location for a total of three scanners. Since the CON was issued, Novant has not implemented this project, and the approved scanner remains unutilized. In addition, Novant currently owns one mobile MRI scanner which is operating below utilization performance standard. Based on these deficiencies, Novant Health, Inc. fails to demonstrate the need for the proposed fixed MRI scanner in Clemmons. Since Novant has been unwilling or unable to develop the previously-approved MRI project, their predictions for future MRI utilization are most unreliable.

The patient origin projections for the proposed Clemmons fixed MRI are unreasonable. The patient origin data is calculated from the annualized FFY 2009-2010 scans from Piedmont Imaging, FMCI-Maplewood, FMCI-Winston Salem Healthcare and FMCI-Kernersville and it assumes that all scans from certain zip codes will shift to the Clemmons site. However, the patients in these zip codes already have abundant access to other MRI scanners, including the previously listed facilities as well as mobile sites in Davie County. To claim that all MRI scans from these zip codes will be diverted from the nearby existing facilities is unreasonable. The applicant's explanation that "ongoing growth and aging of the service population" will compensate for this transfer is unsupported because statewide MRI demand shows minimal growth. Furthermore, the chart on page 54 shows that MRI volume has been decreasing at Piedmont Imaging since 2004 and at FMCI-Maplewood since 2008. It is unreasonable to assume that all MRI procedures from the specific zip codes (27012, 27023, 27006, and 27028) will be diverted from other Novant sites to the proposed Clemmons MRI.

Novant repeatedly cites the high utilization of its existing scanners, but also continually excludes the data for the fixed scanner that has not been implemented. The utilization rate on page 70 of the application is misleading in its calculation that Novant health-related MRI units are operating at 93.5 percent. If the applicant had included the fixed MRI scanner that was approved in 2007, and which has a utilization rate of zero, the percent of maximum capacity falls to 71.7 percent.

Novant owns the Forsyth Medical Center mobile MRI scanner which provides services to Forsyth County. The performance standards require an applicant to demonstrate that existing mobile MRI scanners in the proposed service area performed 3,328 weighted MRI procedures in the most recent 12 month period; Novant's mobile MRI scanner has performed only 2,969 weighted scans between July 1, 2009 and June 30, 2010. Despite Novant's assurances that the mobile MRI volume will increase, the scanner does not meet the regulatory criteria.

The application provides inconsistent information regarding the location and utilization of existing fixed MRI scanners. Novant is incapable of stating when and where their approved fixed MRI scanner (CON #G-7919-07) will be operating, and therefore cannot conclusively project the volumes of each MRI facility location. The weighted volume projections on page 59 of the application predict the usage of three fixed scanners at Forsyth Medical Center and base it's volume on this prediction, but Exhibit 30 shows that Novant has taken measures to move one scanner from Forsyth Medical Center to Kernersville Medical Center, which is currently under construction and is scheduled to open in 2011.

- (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.*

The Novant application fails to conform to CON Review Criterion 4 because the application is nonconforming to Criteria 3 and 6. The utilization projections are overstated and unreliable. Furthermore, Novant has no unmet need for additional MRI capacity. Consequently, the application fails to demonstrate that the project is an effective alternative.

- (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.*

The Novant application fails to conform to CON Review Criterion 5 because the utilization projections are overstated and unreliable. Please see the comments regarding CON Review Criterion 3.

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

Novant's application for an additional MRI scanner at the Clemmons location, or anywhere in Forsyth County, represents unnecessary duplication of services. Novant currently has a mobile scanner that is underutilized and an approved fixed MRI scanner (CON #G-7919-07) that it has failed to implement in a timely manner.

*(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

**The Novant application does not comply with Criterion 18a because the application is nonconforming with CON Review Criteria 3, 4, and 5. Utilization projections are overstated due to unreasonable assumptions regarding the expected shift of patients from other facilities and unreasonable patient origin.**

**In addition to being nonconforming with CON Review Criteria, the Novant application is also nonconforming with MRI criteria and standards:**

*10A NCAC 14C.2702 (c) (5) documentation of the need for an additional MRI scanner in the proposed service area and description of the methodology used to project need, including all assumptions regarding the population to be served;*

**The Novant application does not meet this standard because the methodology and assumptions are unreasonable and result in inaccurate and overstated utilization projections as discussed regarding Criterion 3.**

*10A NCAC 14C.2703 (b) (2) that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data. [Notes: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]*

**Novant owns the Forsyth Medical Center mobile MRI scanner which provides services to Forsyth County. The performance standards require an applicant to demonstrate that existing mobile MRI scanners in the proposed service area performed 3,328 weighted MRI procedures in the most recent 12 month period; Novant's mobile MRI scanner has performed only 2,969 weighted scans between July 1, 2009 and June 30, 2010. Despite Novant's assurances that the mobile MRI volume will increase, the scanner does not meet the regulatory criteria.**