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By Kelli Fisk at 2:51 pm, Aug 08, 2008

August 8, 2008

Ms. Carol Potter, Planner  
NC Division of Health Service Regulation  
Medical Facilities Planning Section  
701 Barbour Drive  
Raleigh, NC 27603

RE: Novant Health, Inc. and MedQuest, Inc. Comments Regarding Carolinas Healthcare System (CHS) Petition Filed August 1, 2008 for a Moratorium on Mobile MRI scanner need in the 2009 SMFP

Dear Ms. Potter:

We appreciate the opportunity to comment on the above referenced petition which requests adjustment to the 2009 State Medical Facilities Plan (SMFP) to include language specific to mobile MRI scanners. In addition, CHS recommends the establishment of a workgroup to develop a need methodology for mobile MRI scanners and asserts that the current need determination methodology creates unnecessary duplication of MRI scanners. CHS's petition also suggests a one-year moratorium on the approval of additional mobile MRI scanners in the state. The SMFP fixed MRI scanner need method was significantly overhauled and updated in 2004 and has been in use since the 2005 SMFP. As explained below, we do not think there are any fundamental flaws with the current MRI need method, such that either a moratorium on mobile MRI scanners or a workgroup on the fixed MRI need method is necessary at this time.

Given the population growth and subsequent growth in healthcare services within many areas of the state, there may be situations where a mobile MRI scanner is needed. For example, Novant Health has community hospitals in development in Mint Hill and Kernersville without fixed MRI capability. An additional mobile scanner may be necessary to provide MRI services to patients in these communities until a fixed scanner is feasible. We also assert that many hospitals, diagnostic imaging centers or other healthcare providers in the state may also wish to retain the ability to apply for a mobile MRI scanner if necessary to provide care for their patients.

Mobile MRI scanners often function as a meaningful alternative for those providers experiencing increased capacity or awaiting approval of a fixed MRI scanner. Most, if not all, fixed MRI scanner certificate-of-need (CON) applications are highly competitive and often result in further litigation once the decision has been rendered. The CON review time and extended litigation often means that there is a two or three year delay before a fixed scanner becomes operational. However, existing, approved mobile MRI scanners may be utilized through a contract with an existing mobile MRI scanner until the final approval of the fixed scanner is determined. In the alternative, an applicant may choose to file a CON application for its own mobile MRI scanner to address its MRI diagnostic imaging needs.



MRI technology is rapidly becoming the standard of care in a variety of specialties. Compared to other imaging modalities, MRI has been in clinical use for only a short time and yet it has already offered significant improvement in the diagnosis and treatment of patients. Unlike other forms of imaging, it is virtually risk-free and non-invasive to patients and the number of images that may be performed on an individual is theoretically limitless. With advances in cardiac and breast imaging, the use of MRI scans is only expected to increase. Therefore, it is not necessary to limit access to such a valuable diagnostic tool by proposing that no mobile MRI scanners be approved in the next calendar year, especially when the CON Section, as CHS acknowledges, only issues CON's if an applicant can actually demonstrate a need for the proposed mobile MRI services.

The state's current MRI need methodology does not create unnecessary duplication of services. First of all, one of the key purposes of CON regulation is to avoid duplication while at the same time providing and encouraging enhanced access to services. State planners must evaluate every CON application using Review Criterion 6 (which addresses unnecessary duplication of services) and make these determinations on a case by case basis.

The state's tiered methodology and weighting for fixed MRI services is also a need determination formula that appropriately considers the number of fixed and mobile MRI scanners, as well as the complexity and variety of the procedures performed by each provider. It has evolved over time so that the state may evaluate the need for fixed MRI scanners in a complex healthcare environment.

The utilization of mobile MRI scanners in the state has not negatively impacted the need for fixed MRI scanners as evidenced in the recent years as shown in the chart below:

SMFP Year	Number of Fixed MRI Needed per SMFP
2005	17
2006	6
2007	7
2008	11
2009	7

Source: Chapter 9, State Medical Facilities Plans 2005, 2006, 2007, 2008, Draft 2009

Moreover, the state has approved *additional* fixed scanners outside of the above fixed MRI scanner need determinations for specialized pediatric (2005 SMFP), breast (2006 SMFP), extremity (2006 SMFP), and upright/multi-positional (2008 SMFP) MRI scanners to be acquired. The broad-based demand for both general use and specialized MRI scanners within the state plan reinforces that there is a strong and ongoing need for fixed scanner services, as well as mobile MRI services to accommodate the demand for these important diagnostic services.

In summary, MRI services, including those provided by mobile MRIs, are increasingly becoming the most effective imaging tool in a variety of cases and specialties. The state should ensure that patients and physicians have ready access and timely availability to these services. Therefore, we

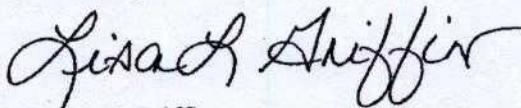


Ms. Potter  
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do not support anything as extreme as a moratorium on mobile MRI scanner applications for 2009.  
Nor do we support any change in the MRI need methodology or language presented in the draft  
2009 SMFP.

Thank you for your consideration of our comment concerning CHS's petition to seek a moratorium  
on mobile MRI scanners and to request the formation of an MRI scanner need method work group.  
Please contact me if you have any questions.

Sincerely,



Lisa L. Griffin  
Manager, Certificate of Need  
Novant Health, Inc.

Cc: Greg Beier, Novant Health  
Fred Hargett, Novant Health  
Todd Latz, MedQuest

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