

October 14, 2016



VIA E-MAIL

Nadine Pfeiffer  
Rules Review Manager  
North Carolina Department of Health Service Regulation  
NC Department of Health and Human Services  
2701 Mail Service Center  
Raleigh, North Carolina 27699-2701

2085 Frontis Plaza Boulevard  
Winston Salem, NC 27103

novanthealth.org

Re: Proposed Repeal of the Diagnostic Center and Major Medical Equipment CON rules

Dear Ms. Pfeiffer:

Novant Health, Inc. and its legal affiliate MedQuest Associates, Inc. (collectively "Novant Health") support the DHSR CON Section's efforts to repeal the CON diagnostic center and major medical equipment rules found at 10A N.C.A.C. 14C.1801-.1804 ("Diagnostic Center Rules") and N.C.A.C. 14C.3101-.3104 ("Major Medical Equipment Rules").

As an initial matter, the Diagnostic Center Rules can be burdensome for healthcare provider applicants to comply with, which makes it challenging for the CON Agency to administer. For example, the Rules require that an applicant submit, as part its CON application, specific detailed information regarding the volume and capacity levels of other healthcare providers in a given service area. This information, however, is unavailable to the majority of the applicants since non-hospital healthcare providers are not currently required to report data regarding mammography, ultrasound, x-ray services and other similar services. Without public access to the information required by the Diagnostic Center Rules, it is extremely difficult and burdensome for an applicant to comply with said rules.

In addition, the Diagnostic Center Rules specifically require an applicant to demonstrate that all other providers in the proposed service area are operating at or above 80% capacity with regard to the equipment or service applied for. There are two problematic issues with this particular provision of the Diagnostic Center Rules. First, there is no standard definition of capacity for each possible type of equipment that an applicant is seeking. Second, there is no way for an applicant to determine true capacity for another provider due to the lack of publicly available information regarding other providers' staffing levels, hours of operation, individual procedure time as well as other factors that may impact capacity. Consequently, the Diagnostic Center Rules prevent an applicant from having a fair opportunity to demonstrate need for its Diagnostic Center project and the Department's proposal to repeal said rules should be granted.

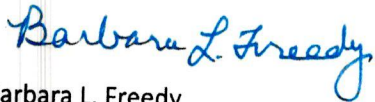
Novant Health also supports the Department's proposal to repeal the Major Medical Equipment Rules as said rules also contain the problematic requirement that an applicant must show- the impact that its proposed new major medical equipment will have on other providers in the service area. As previously discussed, the data concerning other facilities is not typically publicly available.

We commend and support the CON Agency's efforts to modernize and streamline the Certificate of Need process for diagnostic center and major medical equipment applications. It is important to note that the proposed repeal of these rules will still require an applicant to demonstrate in its CON Application for either new Major Medical Equipment or a Diagnostic Center the need for the project.

And Diagnostic Center and Major Medical Equipment CON Applications will continued to be reviewed by the CON Agency pursuant to the CON statutory review criteria found in the CON law at NCGS Section 131E-183. The CON law<sup>1</sup> still contains definitions for major medical equipment and diagnostic centers as part of the definitions of New Institutional Health Services which require the filing of a CON Application.

The CON Agency's proposed repeal of the rules, however, will likely result in a significantly less burdensome CON review process for diagnostic center and major medical equipment CON applications. This will improve access to needed services and equipment for providers with a demonstrated need to obtain necessary medical equipment in a timely and efficient fashion.

Sincerely,



Barbara L. Freedy  
Director, Certificate of Need  
Novant Health, Inc.



Tiffany Brooks, Manager  
Certificate of Need  
MedQuest Associates, Inc.

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<sup>1</sup>NCGS Sections 131E-176(14o) & (7a).