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Comments In Opposition to Proposed Repeal of Certificate of Need Regulations

Submitted by Wake Radiology

October 13, 2016

As provided by notice dated August 15, 2016, the Department of Health and Human Services, Division of Health Service Regulation ("Department") proposes to repeal the following administrative rules relating to diagnostic centers and major medical equipment:

10A NCAC 14C.1801
10A NCAC 14C.1802
10A NCAC 14C.1804
10A NCAC 14C.3101
10A NCAC 14C.3102
10A NCAC 14C.3104

The stated rationale for the repeal is that the rules "place a burden on applicants establishing diagnostic centers as they require applicants to demonstrate that every other provider of the same service has and will continue to operate at 80% of capacity, this data of which is not publicly available, and non-specific to the type of major medical equipment the applicant is seeking and provide no guidance to the applicant as to what is required."

As explained in these comments, we object to the repeal of these rules and believe the Department should not repeal these rules in their entirety. To the extent changes are needed to the rules, these comments provide alternative language for the rules which would address the Department's stated concern that an unnecessary burden not be placed on applicants, yet would preserve the integrity of the CON process as applied to diagnostic centers and major medical equipment.

The Regulations Contain Critical Definitions

Importantly, the CON statutes governing the development of diagnostic centers and the acquisition of major medical equipment are not changing. A CON is still required for development of a diagnostic center and the acquisition of major medical equipment, and certain terms used in the CON statutes applicable to these activities are defined in the regulations. Therefore, it is important to retain the definitions in these regulations so that the statute can be fully understood and fairly applied.

For example, in determining whether the costs incurred by a facility, program, or provider would contribute to the $500,000 threshold under NCGS § 131E-176(7a) for a "diagnostic center," the statute instructs that certain costs which are "essential to acquiring and making operational the equipment" should be included. (emphasis added) The term "essential" is not defined in the statute; instead, the definition of "essential" instead appears in 10A NCAC 14C.1802.

If this definition is repealed, providers will have no statutory or regulatory guidance about what costs must be considered for purposes of determining whether their facility is a "diagnostic center." This uncertainty could also provide fertile ground for abuse, and costs which are currently required to be included could be left out by providers in an effort to circumvent the CON process if the rules are repealed.

A Majority of the Regulations Do Not Place an Undue Burden on Applicants, and Revisions can Address this Issue.

The notice from the Department stated that the regulations proposed to be repealed place a burden on applicants because they require information about other providers, which is not publicly available. However, only two subparts of one regulation, 10A NCAC 14C.1804, require such utilization information about other providers. Therefore, the rationale given by the Department only applies to those two subparts, and is not applicable to the other regulations proposed to be repealed. No other rationale for the repeal of these six rules is provided.

Additionally, to the extent these two rules (10A NCAC 14C.1804(1) and 10A NCAC 14C.1804(2)) pose a burden on applicants, the rules could be revised in a way that addresses the problem without wholesale repeal.

The following two rules require information about the utilization of other providers in the service area.

- 10A NCAC 14C.1804(1) requires an applicant to show that all existing medical equipment (similar to the equipment proposed) in the proposed service area is operating at 80% of its capacity.
- 10A NCAC 14C.1804(2) requires an applicant to show that all existing and approved medical equipment (similar to the equipment proposed) in the proposed service area is projected to operate at 80% of its capacity.

(emphasis added)

In order to provide this information, an applicant would need information about the utilization of other providers in the service area, and the projections for utilization of other providers in the service area. This information is not publicly available for many modalities, but the logical reason for the rules merits their replacement, not repeal. Among other things, the rationale behind these rules is that before the Department approves the development of additional diagnostic centers, the applicant must show that the equipment in the service area is already highly utilized, and that the applicant will not be adding excess capacity that is unnecessarily duplicative of existing providers.

While the rules may place a burden on applicants, they play a very important role in requiring an applicant to demonstrate that its project is truly needed by the patients it proposes to serve. Thus, instead of wholesale repeal of these regulations, they could instead be revised to remove any burden but still serve as a safeguard against unneeded expenditures.

Instead of requiring an applicant to demonstrate that all equipment in the proposed area is operating at 80%, the applicant should instead be required only to demonstrate that its own equipment is operating at 80%. Additionally, instead of requiring an applicant to demonstrate that all existing and approved equipment in the proposed area is projected to operate at 80%, the applicant should instead be required only to demonstrate that its own equipment is projected to operate at 80%. For example, if an applicant has some major medical equipment and proposes to acquire an additional piece of equipment that would

make its facility a diagnostic center, it would be required to demonstrate that it is currently operating its equipment at 80% utilization, and that after acquisition of the additional equipment it is projected to be operating its equipment at 80%.

This revision would require applicants to demonstrate that its proposal is needed, and that the public would have insufficient access but for its equipment. For example, if utilization of equipment is below 80%, there is sufficient capacity to treat additional patients and access to the equipment is likely adequate to meet patients' needs without acquiring additional equipment. However, high utilization of an applicant's existing equipment indicates a demand for the services and the need for additional equipment. An applicant with highly utilized equipment over 80% can thus demonstrate that patients in the service area will not have adequate access unless the applicant's proposed project is approved. In accordance with the requirements of the CON law, the revised rules would require an applicant to demonstrate that its project is needed by the public.

These two rules could be revised to read as follows:

10A NCAC 14C.0184 (After proposed revision)

An applicant proposing to establish a new diagnostic center or to expand an existing diagnostic center shall provide:

(1) documentation that all of the applicant's existing medical diagnostic equipment providing services is operating at 80% of the maximum number of procedures that the equipment is capable of performing for the twelve month period immediately preceding the submittal of the application;

(2) documentation that the applicant's proposed medical diagnostic equipment is projected to be utilized at 80% of the maximum number of procedures that the equipment is capable of performing by the fourth quarter of the third year of operation following initiation of diagnostic services.

10A NCAC 14C.0184(3) and (4) would remain unchanged.

Regulatory Changes Cannot Be Effected through the CON Application Form

The rationale for the repeal also appears to cite the Department's ability to change the CON application form to request the necessary information from applicants. However, significant changes to the information requested in the application form could result in an end-run around the administrative rule-making process. The Department should be subject to the rule-making process in accordance with the Administrative Procedure Act (NCGS § 150B) and should be required to provide public notice and allow for public comment before making such changes.

Repeal of Rules Relating to "Need" Undermine the Purpose of the CON Law

Finally, just as the performance standards for diagnostic centers require information from applicants which helps them demonstrate the need for their project, the rules for major medical equipment also provide needed specifics and guidance on how an applicant can demonstrate the need for its project in order to comply with Criterion 3, NCGS § 131E-183(a)(3). The rule at 10A NCAC 14C.3104 is entitled "Need for Services" and lists information an applicant must include in its application. To the extent the

information listed is evaluated and analyzed by the Department in determining whether an applicant has demonstrated need for major medical equipment, these rules are important.

Conclusion

Wake Radiology opposes the wholesale repeal of the regulations applicable to diagnostic centers and major medical equipment, as proposed by the Department. Instead, Wake Radiology urges the Department to revise the rules as described herein. These revisions would maintain the integrity of the CON process while addressing the concern of placing an unnecessary burden on applicants.

Lyndon Jordan MD

Lyndon Jordan, M.D.
Wake Radiology