



Eastern Radiologists, Inc.

Comments on Proposed Repeal of Certificate of Need Regulations
October 11, 2016

It appears, based on a letter dated August 15, 2016, that certain rules governing diagnostic centers and major medical equipment (10A NCAC 14C.1801, .1804, .3101, .3102, and .3104) are proposed to be repealed by the Department of Health and Human Services, Division of Health Service Regulation (“Department”).

The Department should not repeal these rules. They provide important information and guidance to CON applicants, and they serve as an important safeguard to ensure that the services proposed by an applicant are truly needed by the population proposed to be served. Repeal of these rules would allow for the development of unneeded and unnecessarily duplicative services, which is contrary to the purpose of the CON Law. For the reasons stated in these comments, we object to the repeal of these rules.

A. The Agency Cannot Use the CON Application Form In Place of Administrative Rules.

As an initial matter, the notice from the Department appears to suggest that the CON application form is an appropriate vehicle for specifying what information is necessary to evaluate a project pursuant to N.C. Gen. Stat. § 131E-183(a). While the Department does have the authority to request information designed to address the statutory requirements for CON review, the application form does not have the force of law. The application form is not subject to the process for rule-making and thus the Department’s use of the application form as a means to provide guidance to applicants or change the information requested from applicants does not provide the same procedural safeguards as the administrative rule-making process. Any changes to the type of information requested of an applicant, or any changes to how a CON application will be reviewed, should be done as prescribed in the Administrative Procedure Act (N.C. Gen. Stat. § 150B-1, *et seq.*), and not through informal changes or revisions to the CON application form.

B. Any Undue Burden on Applicants Can be Removed From the Current Rule with Revisions.

The reason given by the Department for the repeal is that the regulations place an undue burden on applicants because they require non-public information about other providers of the service being proposed. There is no other reason given for the proposed repeal of the rules. Despite the stated rationale of the Department, there are only two portions of one rule (10A NCAC 14C.1804) which request this type of information. They are:

Pursuant to 10A NCAC 14C.1804(1), an applicant must show that all existing medical equipment (similar to the equipment proposed) in the proposed service area is operating at 80% of its capacity.

Pursuant to 10A NCAC 14C.1804(2), an applicant must 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.

As the only two subparts which pose such a burden, the Department could revise the rules to remove the burden while retaining the purpose behind the rules.

The concept behind these rules is particularly important to retain. These rules ensure that new diagnostic centers cannot be developed unless and until the applicant demonstrates to the Department that they are truly needed, and that the existing centers are already operating at or near their capacity. This assists the applicant in demonstrating that the public needs the additional capacity proposed in the CON application. This purpose is fundamental to the CON law, and it should be preserved. However, some revisions to these rules could accomplish the Department's desire to lighten the burden on applicants without undermining the purpose of the CON law.

The Department's criticism of these rules appears focused on the burden of obtaining information about other providers. However, there is no undue burden on an applicant to provide information about itself or its utilization of existing equipment when it is applying to develop a diagnostic center. Therefore, the requirements in place regarding 80% utilization could be retained only as they apply to an applicant's own existing or approved equipment. This information is readily available and is important to an applicant's demonstration of need for its new project. Requiring this information is also consistent with the CON law's purpose of preventing the development of unneeded health care facilities and services.

To accomplish this revision, we proposed that the rule at 10A NCAC 14C.0184 be revised with the bold language below:

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;**
- (3) documentation that the applicant's utilization projections are based on the experience of the provider and on epidemiological studies; and**
- (4) all the assumptions and data supporting the methodologies used for the projections in this Rule.**

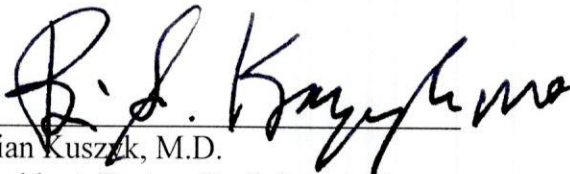
C. The Regulations Provide Guidance to Applicants for Certificates of Need.

Finally, even if these rules are repealed, the related statutes would remain in effect, and the administrative rules at issue are helpful in explaining these statutes. Thus, it would be helpful to applicants if these rules are simply amended, rather than repealed. The statutes applicable to diagnostic centers and the acquisition of major medical equipment would remain in place, and the development of a diagnostic center or the acquisition of major medical equipment would have to be accomplished in a manner that is consistent with these statutes. However, if the Department repeals the rules which help clarify the statutes, CON applicants would no longer have the benefit of this useful guidance.

By way of example, there are terms used in the CON statutes which are not defined. However, these terms are defined in the administrative rules. Without the administrative rules to explain these defined terms, the CON statute becomes less clear and more susceptible to confusion or misinterpretation by applicants. In order to provide all applicants with the same set of rules and a level playing field when attempting to comply with the CON statutes, these administrative rules should be retained.

D. Conclusion

Eastern Radiologists, Inc. submits these comments in opposition to the repeal of the regulations applicable to diagnostic centers and major medical equipment. We urge the Department to either leave the administrative rules in question intact, or to revise the rules as proposed in these comments to accomplish the Department's stated purpose without damaging the process that providers have been working hard to comply with for many years.

A handwritten signature in black ink, appearing to read "B. J. Kuszyk". The signature is written in a cursive, flowing style.

Brian Kuszyk, M.D.

President, Eastern Radiologists, Inc.