

North Carolina Department of Health and Human Services Division of Health Service Regulation

Pat McCrory Governor Richard O. Brajer Secretary

Mark Payne, Director Health Service Regulation

MINUTES OF PUBLIC HEARING October 6, 2016 10:00 A.M.

Division Staff Present:

Nadine Pfeiffer, Rule-making Coordinator, DHSR Martha Frisone, Assistant Section Chief, DHSR Certificate of Need Section Diana Barbry, Rule Making Assistant, DHSR

Others Present:

Amber George, Raleigh Radiology
Nathan Marvelle, Ascendient Healthcare
Jon Rogers, PDA
David Meyer, Keystone Planning
Laura Puryear, Walk West
Elizabeth Hedrick, Smith Moore
Marc Hewitt, Smith Moore
Frank Kirshbaum, Wyrick Robbins
Lyndon Jordon, MD, Wake Radiology
Karin Sandler, Keystone Planning
Jon Carr, Jordon Price
Tiffany Brooks, Medquest

1. Purpose of Hearing

The purpose of this public hearing was to solicit verbal and/or written comments from the public on the proposed repeal of 6 rules for Certificate of Need, specifically 10A NCAC 14C .1801, .1802, .1804, .3101, .3102, and .3104. There is no fiscal note required for rule repeals.



Office of the Director

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2. Hearing Summary

The Public Hearing was opened by Nadine Pfeiffer at 10:02 am. Attending were representatives from the provider community and advocacy organizations. A total of four oral comments were recorded. A summary of these comments is as follows:

- 1. Amber George from Raleigh Radiology spoke in support the rules, stating that she disagreed with the hospital objection to the proposed repeal because the CON Diagnostic Center rules were antiquated and the practice of medicine has evolved significantly since these rules were codified in 1993. The Diagnostic Center rules have long been considered to be problematic and the proposed rules repeal is an appropriate and necessary solution to the problem. The repeal will not diminish the agency's ability to fully evaluate a CON application's conformity to statutory review criteria. The Acute Care/Medical Equipment form adequately request all information necessary for the agency to conduct its review. The rules are cumbersome and request information typically not publically available. These rules are anti-competitive and create a built-in conflict of interest by enabling a CON applicant's opponent to thwart competition by submitting unverifiable data during CON public comment period. The rules are completely unnecessary for replacing existing medical diagnostic equipment already in use because utilization of other similar equipment is not relevant in those CON reviews. The repeal of the rules will improve the public access and reduce cost without any reduction in the quality of care.
- 2. Mark Hewitt from Smith Moore spoke in support of the rules stating that he agrees with the agency's decision for the rule change because this particular rule is subject to abuse by those who propose an application to establish a diagnostic center because there are no particular definitions or particular metrics for measuring for capacity utilization and competing providers can create their own numbers for utilization to remain below the threshold needed to receive new equipment. For these reasons he agrees with the rule changes.
- 3. Frank Kirshbam from Wyrick Robbins agrees that the rule needs to be rewritten, but spoke in opposition to the repeal of the rules, stating that the repeal of the rules could be problematic because there is no effective benchmark to measure use and that could cause unnecessary applications to be approved and that leads to other kinds of abuse. Demonstrating to 80% utilization of others volumes when applicants do not have access to others volume numbers is unfair but requiring a demonstration of some sort of need and an applicant to demonstrate its own utilization that has its own diagnostic center is fair and equitable and is a benchmark for all parties to determine need. That's an agreement for why there is a need for rules, if there is a statute, you don't need rules I think you need rules.

4. David Myer from Keystone Planning spoke in support of the rules, stating that the CON application form and the statutory review criteria are mechanisms in place for evaluating the reasonableness of an applicant to project need. There is no need for this rule, especially for replacement equipment. There is a standard in Criterion 3 for the applicant to demonstrate reasonableness. The agency can evaluate the need from questions in the application form and Criterion 3, the law.

In addition, a total of one written comment was given to the Agency in support of the rules.

These comments will be taken into consideration prior to the Division adopting the proposed rules and submitting them to the Rule Review Commission for approval. The hearing was adjourned at 10:10 a.m.

Respectfully Submitted,

Nadine Pfeiffer, Rule-making Coordinator

October 6, 2016

Madine Pfeiffer

Attachment

Public Hearing Attendance Certificate of Need Rules 10A NCAC 14C .1801, .1802, .1804, .3101, .3102 and .3104

October 6, 2016 10:00 a.m.

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Nathen Marvelle	Ascerdient	N
Lon Rodgers	PDA	\wedge
David Meyer	Key stone Manning	16 Y (9)
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