



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**
Division of Health Service Regulation

ROY COOPER • Governor
MANDY COHEN, MD, MPH • Secretary
MARK PAYNE • Director

*Revised 11/7/19

MEMORANDUM

DATE: November 7, 2019
TO: Interested Parties
FROM: Nadine Pfeiffer, Rule Review Manager *MP*
RE: Proposed Temporary Amendment of Certificate of Need Rules

GS 150B-21.1 requires a rule-making body to notify certain individuals of its intent to publish a temporary rule on the Office of Administrative Hearings website. It also requires notification of the date, time and location of the public hearing on the rules.

The N.C. Department of Health and Human Services/Director, DHSR has submitted form OAH 0700 to the Codifier of Rules, Office of Administrative Hearings, indicating its intent to amend the following Certificate of Need rule through temporary procedures to be made consistent with the 2020 State Medical Facilities Plan:

10A NCAC 14C .2203 Performance Standards

The public hearing is scheduled for December 5, 2019 at 10:00 a.m. in Room 026, Edgerton Building, 809 Ruggles Drive, Raleigh, NC 27603. The building is in the Dorothea Dix Park. Ms. Nadine Pfeiffer, DHSR Rule-Review Manager, is accepting public comments on this rule from November 18, 2019 – *December 11, 2019. Comments can also be made at the public hearing. The proposed effective date of this rule is February 1, 2020. A copy of the proposed rule is attached to this memo and can also be found at the Division of Health Service Regulation web site <https://info.ncdhhs.gov/dhsr/ruleactions.html>.

Please feel free to contact the Health Care Planning and Certificate of Need Section at (919) 855-3873, should you have questions related to this memorandum or the proposed rule.

Enclosures

cc: Mark Payne, Director, Health Service Regulation
Emery Milliken, Deputy Director, DHSR
Martha Frisone, Chief, Healthcare Planning and Certificate of Need Section
Joel Johnson, Assistant General Counsel, DHHS
Lisa Pittman, Assistant Chief, Certificate of Need

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • DIVISION OF HEALTH SERVICE REGULATION

OFFICE OF THE DIRECTOR

LOCATION: 809 Ruggles Drive, Edgerton Building, Raleigh, NC 27603
MAILING ADDRESS: 2701 Mail Service Center, Raleigh, NC 27699-2701
<https://info.ncdhhs.gov/dhsr/> • TEL: 919-855-3750 • FAX: 919-733-2757

AN EQUAL OPPORTUNITY / AFFIRMATIVE ACTION EMPLOYER

1 10A NCAC 14C .2203 is proposed for amendment under temporary procedures as follows:

2
3 **10A NCAC 14C .2203 PERFORMANCE STANDARDS**

4 ~~(a) An applicant proposing to establish a new End Stage Renal Disease facility shall document the need for at least~~
5 ~~10 stations based on utilization of 3.2 patients per station per week as of the end of the first operating year of the~~
6 ~~facility, with the exception that the performance standard shall be waived for a need in the State Medical Facilities~~
7 ~~Plan that is based on an adjusted need determination. An applicant proposing to establish a new kidney disease~~
8 ~~treatment center or dialysis facility shall document the need for at least 10 dialysis stations based on utilization of 2.8~~
9 ~~in-center patients per station per week as of the end of the first 12 months of operation following certification of the~~
10 ~~facility. An applicant may document the need for less than 10 stations if the application is submitted in response to an~~
11 ~~adjusted need determination in the State Medical Facilities Plan for less than 10 stations.~~

12 (b) ~~An applicant proposing to increase the number of dialysis stations in an existing End Stage Renal Disease facility~~
13 ~~or one that was not operational prior to the beginning of the review period but which had been issued a certificate of~~
14 ~~need shall document the need for the additional stations based on utilization of 3.2 patients per station per week as of~~
15 ~~the end of the first operating year of the additional stations. An applicant proposing to increase the number of dialysis~~
16 ~~stations in:~~

17 (1) an existing dialysis facility; or

18 (2) a dialysis facility that is not operational as of the date the certificate of need application is submitted
19 but has been issued a certificate of need;

20 shall document the need for the total number of dialysis stations in the facility based on 2.8 in-center patients per
21 station per week as of the end of the first 12 months of operation following certification of the additional stations.

22 (c) An applicant shall provide all assumptions, including the methodology by which patient utilization is projected.

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24 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
25 *Temporary Adoption Eff. January 1, 2003; January 1, 2002;*
26 *Eff. April 1, 2003;*
27 *Amended Eff. August 1, 2004;*
28 *Temporary Amendment Eff. January 1, 2005;*
29 *Amended Eff. November 1, 2005;*
30 *Temporary Amendment Eff. February 1, 2006;*
31 *Amended Eff. November 1, 2006;*
32 *Temporary Amendment Eff. February 1, 2010;*
33 *Amended Eff. November 1, 2010;*
34 *Temporary Amendment Eff. February 1, 2020.*