



TEMPORARY RULE-MAKING FINDINGS OF NEED

[Authority G.S. 150B-21.1]

OAH USE ONLY

VOLUME:

ISSUE:

1. Rule-Making Agency: N.C. Department of Health and Human Services/Director, DHSR

2. Rule citation & name: 10A NCAC 14C .2203 Performance Standards

3. Action: ☐ Adoption ☒ Amendment ☐ Repeal

4. Was this an Emergency Rule: ☐ Yes ☒ No Effective date:

5. Provide dates for the following actions as applicable:

- a. Proposed Temporary Rule submitted to OAH: 11/07/19
- b. Proposed Temporary Rule published on the OAH website: 11/14/19
- c. Public Hearing date: 12/05/19
- d. Comment Period: 11/18/19 – 12/11/19
- e. Notice pursuant to G.S. 150B-21.1(a3)(2): 11/07/19
- f. Adoption by agency on: 01/07/20
- g. Proposed effective date of temporary rule [if other than effective date established by G.S. 150B- 21.1(b) and G.S. 150B-21.3]: 02/01/20
- h. Rule approved by RRC as a permanent rule [See G.S. 150B-21.3(b2)]: n/a

6. Reason for Temporary Action. Attach a copy of any cited law, regulation, or document necessary for the review.

- ☐ A serious and unforeseen threat to the public health, safety or welfare.
- ☐ The effective date of a recent act of the General Assembly or of the U.S. Congress.
Cite:
Effective date:
- ☐ A recent change in federal or state budgetary policy.
Effective date of change:
- ☐ A recent federal regulation.
Cite:
Effective date:
- ☐ A recent court order.
Cite order:
- ☒ State Medical Facilities Plan.
- ☐ Other:

Explain: Several subject matters are addressed in the State Medical Facilities Plan (SMFP). Changes were made to the chapter in the 2020 SMFP addressing the End-Stage Renal Disease Dialysis Facilities need methodology. Revisions to an existing Certificate of Need rule are required to compliment or to be made consistent with the SMFP signed by the governor on December 4, 2019. The effective date of the 2020 SMFP is January 1, 2020.

7. Why is adherence to notice and hearing requirements contrary to the public interest and the immediate adoption of the rule is required?

The change to the existing Certificate of Need (CON) performance standards rule for the criteria and standards for end-stage renal disease services is required to compliment or to be made consistent with the State Medical Facilities Plan (SMFP) that will become effective January 1, 2020. The end-stage renal disease dialysis facilities need determination methodology underwent substantial changes by means of interested parties' meetings directed by the State Health Coordinating Council (SHCC) and held by the agency. As a result, the development of the Semiannual Dialysis Report ceased following the July 2019 issue. In addition, approved for inclusion in the 2020 SMFP by the SHCC, the end-stage renal disease dialysis facilities need determinations and methodologies were relocated from Chapter 14 to a revised Chapter 9 of the SMFP that was subsequently signed for approval by the governor on December 4, 2019. This rule reflects the methodology changes in the SMFP and is being adopted under temporary procedures so that correct performance standards reflective of the need methodology changes shall be used by 2020 CON applicants for end-stage renal disease dialysis services. This temporary rule adoption is required for an applicant's compliance with a CON application submission for an end-stage renal disease dialysis facilities' need determination in the 2020 SMFP.

8. Rule establishes or increases a fee? (See G.S. 12-3.1)

☐ Yes

Agency submitted request for consultation on:
Consultation not required. Cite authority:

☒ No

9. Rule-making Coordinator: Nadine Pfeiffer

Phone: 919-855-3811

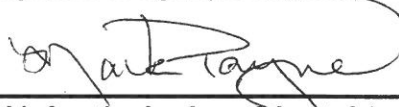
E-Mail: Nadine.pfeiffer@dhhs.nc.gov

Agency contact, if any: Martha Frisone, Chief

Phone: 919-855-3879

E-Mail: martha.frisone@dhhs.nc.gov

10. Signature of Agency Head*:



* If this function has been delegated (reassigned) pursuant to G.S. 143B-10(a), submit a copy of the delegation with this form.

Typed Name: Mark Payne

Title: Director, Division of Health Service Regulation

E-Mail: mark.payne@dhhs.nc.gov

RULES REVIEW COMMISSION USE ONLY

Action taken:

Submitted for RRC Review:

☐ Date returned to agency:

TEMPORARY RULE
REQUEST FOR TECHNICAL CHANGE

AGENCY: DHHS/Division of Health Service Regulation

RULE CITATION: 10A NCAC 14C .2203

DEADLINE FOR RECEIPT: January 10, 2020

PLEASE NOTE: *This request may extend to several pages. Please be sure you have reached the end of the document.*

The Rules Review Commission staff has completed its review of this Rule prior to the Commission's next meeting. The Commission has not yet reviewed this Rule and therefore there has not been a determination as to whether the Rule will be approved. You may call our office to inquire concerning the staff recommendation.

In reviewing this Rule, the staff recommends the following technical changes be made:

Does this Rule apply to kidney disease treatment centers or dialysis facilities at academic medical center teaching hospitals? See G.S. 131E-183(b).

Please retype the rule accordingly and resubmit it to our office at 1711 New Hope Church Road, Raleigh, North Carolina 27609.

Ashley Snyder
Commission Counsel
Date submitted to agency: January 8, 2020

10A NCAC 14C .2203 is amended under temporary procedures as follows:

10A NCAC 14C .2203 PERFORMANCE STANDARDS

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

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

(1) an existing dialysis facility; or

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

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

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

*History Note: Authority G.S. 131E-177(1); 131E-183(b);
Temporary Adoption Eff. January 1, 2003; January 1, 2002;
Eff. April 1, 2003;
Amended Eff. August 1, 2004;
Temporary Amendment Eff. January 1, 2005;
Amended Eff. November 1, 2005;
Temporary Amendment Eff. February 1, 2006;
Amended Eff. November 1, 2006;
Temporary Amendment Eff. February 1, 2010;
Amended Eff. November 1, 2010;
Temporary Amendment Eff. February 1, 2020.*