

1 10A NCAC 14C .2202 is proposed as a temporary rule as follows:

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3 **10A NCAC 14C .2202 INFORMATION REQUIRED OF APPLICANT**

4 (a) An applicant that proposes to increase dialysis stations in an existing certified facility or relocate stations must
5 provide the following information:

- 6 (1) Utilization rates;
- 7 (2) Mortality rates;
- 8 (3) The number of patients that are home trained and the number of patients on home dialysis;
- 9 (4) The number of transplants performed or referred;
- 10 (5) The number of patients currently on the transplant waiting list;
- 11 (6) Hospital admission rates, by admission diagnosis, i.e., dialysis related versus non-dialysis related;
- 12 (7) The number of patients with infectious disease, e.g., hepatitis, and the number converted to
13 infectious status during last calendar year.

14 (b) An applicant that proposes to develop a new facility, increase the number of dialysis stations in an existing
15 facility, establish a new dialysis station, or relocate existing dialysis stations shall provide the following information
16 requested on the End Stage Renal Disease (ESRD) Treatment application form:

- 17 (1) For new facilities, a letter of intent to sign a written agreement or a signed written agreement with
18 an acute care hospital that specifies the relationship with the dialysis facility and describes the
19 services that the hospital will provide to patients of the dialysis facility. The agreement must
20 comply with 42 C.F.R., Section 405.2100.
- 21 (2) For new facilities, a letter of intent to sign a written agreement or a written agreement with a
22 transplantation center describing the relationship with the dialysis facility and the specific services
23 that the transplantation center will provide to patients of the dialysis facility. The agreements
24 must include the following:
 - 25 (A) timeframe for initial assessment and evaluation of patients for transplantation,
 - 26 (B) composition of the assessment/evaluation team at the transplant center,
 - 27 (C) method for periodic re-evaluation,
 - 28 (D) criteria by which a patient will be evaluated and periodically re-evaluated for
29 transplantation, and
 - 30 (E) signatures of the duly authorized persons representing the facilities and the agency
31 providing the services.
- 32 (3) ~~Documentation of standing service from a power company and back up capabilities.~~ that power
33 and water will be available at the proposed site.
- 34 ~~(4) Copies of written policies and procedures for back up for electrical service in the event of a power~~
35 outage.
- 36 ~~(4)~~ (5) For new facilities, the location of the site on which the services are to be operated. If such site is
37 neither owned by nor under option to the applicant, the applicant must provide a written

1 commitment to pursue acquiring the site if and when the approval is granted, must specify a
2 secondary site on which the services could be operated should acquisition efforts relative to the
3 primary site ultimately fail, and must demonstrate that the primary and secondary sites are
4 available for acquisition.

5 ~~(5)~~ (6) Documentation that the services will be provided in conformity with applicable laws and
6 regulations pertaining to staffing, fire safety equipment, physical environment, water supply, and
7 other relevant health and safety requirements.

8 ~~(6)~~ (7) The projected patient origin for the services. All assumptions, including the methodology by
9 which patient origin is projected, must be stated.

10 ~~(7)~~ (8) For new facilities, documentation that at least 80 percent of the anticipated patient population
11 resides within 30 miles of the proposed facility.

12 ~~(8)~~ (9) A commitment that the applicant shall admit and provide dialysis services to patients who have no
13 insurance or other source of payment, but for whom payment for dialysis services will be made by
14 another healthcare provider in an amount equal to the Medicare reimbursement rate for such
15 services.

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17 *History Note: Authority G.S. 131E-177(1); 131E-183(b);*
18 *Eff. March 1, 1989;*
19 *Temporary Amendment Eff. January 1, 2003;*
20 *Amended Eff. August 1, 2004;*
21 *Temporary Amendment Eff. January 1, 2005;*
22 *Amended Eff. November 1, 2005;*
23 *Temporary Amendment Eff. February 1, 2010.*