

## Notes Related to Chapter 14: End-Stage Renal Disease (ESRD) Dialysis Facilities

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No carry-over issues related to the Dialysis Chapter were identified last fall. At this time, no new issues have been presented as petitions or comments for the Committee's consideration in preparing the Proposed 2010 North Carolina State Medical Facilities Plan.

It is important to remember that the Dialysis Chapter is different than other topics in the State Medical Facilities Plan (SMFP). The dialysis methodology appears in both the Proposed and Final versions of the SMFP, but need determinations are not published in the SMFP. Instead, the SMFP requires publication of semiannual determinations of need based on updated patient information from the Southeastern Kidney Council and the Mid-Atlantic Renal Coalition. Those need determinations are issued by staff in January and July as the "North Carolina Semiannual Dialysis Reports." These reports are posted on the DHSR website.

Therefore in preparing the "Proposed SMFP" each year, members consider any changes in dialysis policy or methodology but do not review draft need projections.

In absence of any third party comments or petitions, the Agency recommends no substantive changes for the Proposed 2010 SMFP. Up-dated inventory data have been incorporated into the Dialysis chapter and references to dates have been advanced by one year, as appropriate. Updates are shown in bold.

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## CHAPTER 14

### END-STAGE RENAL DISEASE DIALYSIS FACILITIES

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#### Summary of Dialysis Station Supply and Utilization

Inventories of dialysis facilities and current utilization rates are presented twice a year in “Semiannual Dialysis Reports” required by this chapter. According to the “**January 2009 North Carolina Semiannual Dialysis Report**,” there were **160** End-Stage Renal Disease (ESRD) dialysis facilities certified and operating in North Carolina (*i.e., facilities reporting patient data via the Southeastern Kidney Council*), providing a total of **3,841** dialysis stations. Certificates of need had been issued for an additional **145** dialysis stations, but the stations were not yet certified. Another **128** dialysis stations had been requested, but had not completed the certificate of need review and appeals process. The number of facilities per county ranged from 0 to 13.

Utilization data are based on reported numbers of patients obtained from the Southeastern Kidney Council and the Mid-Atlantic Renal Coalition. Of the **156** certified facilities operational on **June 30, 2008**, **73** were at or above 80% utilization (*i.e., operating with at least 3.2 patients per station*).

#### Changes from the Previous Plan

No substantive changes in the dialysis policy or in the dialysis need methodology have been recommended for the **Proposed 2010 State Medical Facilities Plan**. Dates have been advanced by one year, as needed to represent the time period for the 2009 Plan.

#### Basic Principles

The principles underlying projection of need for additional dialysis stations are as follows:

1. Increases in the number of facilities or stations should be done to meet the specific need for either a new facility or an expansion.
2. New facilities must have a projected need for at least 10 stations (or 32 patients at 3.2 patients per station) to be cost effective and to assure quality of care.
3. The Medical Facilities Planning Section will maintain a list of existing facilities and stations, utilization rates and projected need by county that is up-dated semiannually. Updated projections will be available two times a year on a published schedule. Existing or potential providers interested in expanding in any area of the State may contact the Medical Facilities Planning Section for projected need in the area of interest. (*Note: A dialysis station’s service area is the dialysis station planning area in which the dialysis station is located. Except for the Cherokee-Clay-Graham Multi-County Planning Area and the Avery-Mitchell-*

*Yancey Multi-County Planning Area, each of the 94 remaining counties is a separate dialysis station planning area.)*

4. Updates of the projections may target counties that have developed sufficient need to warrant consideration for facility expansion or for establishment of a new facility. Actual numbers are not published in the Plan so they can be updated as appropriate by the Medical Facilities Planning Section.
5. Home patients will not be included in the determination of need for new stations. Home patients include those that receive hemodialysis or peritoneal dialysis in their home.
6. No existing facility may expand unless its utilization is 80% or greater. Any facility at 80% utilization or greater may apply to expand.
7. Facilities reporting no patients through the Southeastern Kidney Council for four consecutive Semiannual Dialysis Reports, beginning from March 1997, will be excluded from future inventories.
8. Quality of Care: All facilities should comply with Medicare and Medicaid regulations relating to the delivery and certification of ESRD services and with relevant North Carolina statutory provisions. An applicant already involved in the provision of end-stage renal disease services should provide evidence that care of high quality has been provided in the past. The following are considered indicators of quality of care and existing providers proposing to expand their operations should include in their applications data which include, but are not limited to, the following:
  - a. utilization rates
  - b. morbidity and mortality rates
  - c. numbers of patients that are home trained and patients on home dialysis
  - d. number of patients receiving transplants
  - e. number of patients currently on the transplant waiting list
  - f. hospital admission rates
  - g. conversion rates for patients who have acquired hepatitis or AIDS
9. Availability of Manpower and Ancillary/Support Services: The applicant should show evidence of the availability of qualified staff and other health manpower and management for the provision of quality ESRD services as well as the availability of a safe and adequate water supply, provision for treatment of wastewater discharge and a standing electrical service with backup capabilities.
10. Patient Access to In-Center ESRD Services: As a means of making ESRD services more accessible to patients, one of the goals of the N. C. Department of Health and Human Services is to minimize patient travel time to and from the center.

Therefore,

- a. End-stage renal disease treatment should be provided in North Carolina such that patients who require renal dialysis are able to be served in a facility no farther than 30 miles from the patients' homes.
  - b. In areas where it is apparent that patients are currently traveling more than 30 miles for in-center dialysis, favorable consideration should be given to proposed new facilities which would serve patients who are farthest away from existing, operational or approved facilities.
11. Transplantation Services: Transplantation services should be available to, and a priority for, all ESRD patients whose conditions make them suitable candidates for this treatment. New enrollees should meet with and have access to a transplantation representative to provide patient education and evaluation for transplantation.
12. Availability of Dialysis Care: The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for:
- a. Home training and backup for patients suitable for home dialysis in the ESRD dialysis facility or in a facility that is a reasonable distance from the patient's residence;
  - b. ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules;
  - c. Services in rural, remote areas.

### **Sources of Data**

#### ***Inventory Data:***

Data on the current number of dialysis facilities and stations shall be obtained from the Certificate of Need Section and from the Licensure and Certification Section, Division of Health Service Regulation, N. C. Department of Health and Human Services.

#### ***Dialysis Patient Data:***

Data on the dialysis population by county and by facility as of **June 30, 2009** and as of **December 31, 2009** shall be provided by the Centers for Medicare and Medicaid Services (CMS) through the Southeastern Kidney Council, Inc. (SEKC) and the Mid-Atlantic Renal Coalition, Inc.

### **Method for Projecting New Dialysis Station Need**

The Medical Facilities Planning Section (MFPS) shall determine need for new dialysis stations two times each calendar year, and shall make a report of such determinations available to all who request it. This report shall be called the North Carolina Semiannual Dialysis Report (SDR). Relocations of existing dialysis stations within a county shall be reviewed independently (*see Chapter 3, Category I*). The Semiannual Dialysis Reports will

use facility, station and active patient data as of **June 30, 2009** for the “**January 2010 SDR**” and as of **December 31, 2009** for the “**July 2010 SDR.**” A new five-year trend line will be established in the “**July 2010 SDR,**” based on validated data as reported to CMS for the time period ending **December 31, 2009** . Need for new dialysis stations shall be determined as follows:

(1) County Need *(for the **January 2010 SDR** – Using the trend line ending with 12/31/08 data)*

- (A) The average annual rate (%) of change in total number of dialysis patients resident in each county from the end of **2004** to the end of **2008** is multiplied by the county’s **June 30, 2009** total number of patients in the SDR, and the product is added to each county's most recent total number of patients reported in the SDR. The sum is the county's projected total **June 30, 2010** patients.
- (B) The percent of each county's total patients who were home dialysis patients on **June 30, 2009** is multiplied by the county's projected total **June 30, 2010** patients, and the product is subtracted from the county's projected total **June 30, 2010** patients. The remainder is the county's projected **June 30, 2010** in-center dialysis patients.
- (C) The projected number of each county's **June 30, 2010** in-center patients is divided by 3.2. The quotient is the projection of the county's **June 30, 2010** in-center dialysis stations.
- (D) From each county's projected number of **June 30, 2010** in-center stations is subtracted the county's number of stations certified for Medicare, CON-approved and awaiting certification, awaiting resolution of CON appeals, and the number represented by need determinations in previous State Medical Facilities Plans or Semiannual Dialysis Reports for which CON decisions have not been made. The remainder is the county's **June 30, 2010** projected station surplus or deficit.
- (E) If a county's **June 30, 2010** projected station deficit is ten or greater and the January SDR shows that utilization of each dialysis facility in the county is 80% or greater, the **June 30, 2010** county station need determination is the same as the **June 30, 2010** projected station deficit. If a county's **June 30, 2010** projected station deficit is less than ten or if the utilization of any dialysis facility in the county is less than 80%, the county’s **June 30, 2010** station need determination is zero.

(2) County Need *(for the **July 2010 SDR** – Using a new trend line based on 12/31/2009 data)*

- (A) The average annual rate (%) of change in total number of dialysis patients resident in each county from the end of **2005** to the end of **2009** is multiplied by the county's **December 31, 2009** total number of patients in the SDR, and the product is added to each county's most recent total number of patients reported in the SDR. The sum is the county's projected total **December 31, 2010** patients.

- (B) The percent of each county's total patients who were home dialysis patients on **December 31, 2009** is multiplied by the county's projected total **December 31, 2010** patients, and the product is subtracted from the county's projected total **December 31, 2010** patients. The remainder is the county's projected **December 31, 2010** in-center dialysis patients.
- (C) The projected number of each county's **December 31, 2010** in-center patients is divided by 3.2. The quotient is the projection of the county's **December 31, 2010** in-center dialysis stations.
- (D) From each county's projected number of **December 31, 2010** in-center stations is subtracted the county's number of stations certified for Medicare, CON-approved and awaiting certification, awaiting resolution of CON appeals, and the number represented by need determinations in previous State Medical Facilities Plans or Semiannual Dialysis Reports for which CON decisions have not been made. The remainder is the county's **December 31, 2010** projected station surplus or deficit.
- (E) If a county's **December 31, 2010** projected station deficit is ten or greater and the July SDR shows that utilization of each dialysis facility in the county is 80% or greater, the **December 31, 2010** county station need determination is the same as the **December 31, 2010** projected station deficit. If a county's **December 31, 2010** projected station deficit is less than ten or if the utilization of any dialysis facility in the county is less than 80%, the county's **December 31, 2010** station need determination is zero.

### (3) Facility Need

A dialysis facility located in a county for which the result of the County Need methodology is zero in the current Semiannual Dialysis Report (SDR) is determined to need additional stations to the extent that:

- (A) Its utilization, reported in the current SDR, is 3.2 patients per station or greater.
- (B) Such need, calculated as follows, is reported in an application for a certificate of need:
  - (i) The facility's number of in-center dialysis patients reported in the previous Dialysis Report (SDR<sub>1</sub>) is subtracted from the number of in-center dialysis patients reported in the current SDR (SDR<sub>2</sub>). The difference is multiplied by 2 to project the net in-center change for 1 year. Divide the projected net in-center change for the year by the number of in-center patients from SDR<sub>1</sub> to determine the projected annual growth rate.
  - (ii) The quotient from (3)(B)(i) is divided by 12.

- (iii) The quotient from (3)(B)(ii) is multiplied by 6 (*the number of months from **June 30, 2009 until December 31, 2009*** ) for the **January 4, 2010** SDR and by 12 (*the number of months from **December 31, 2009 until December 31, 2010***) for the **July 1, 2010** SDR.
- (iv) The product from (3)(B)(iii) is multiplied by the number of the facility's in-center patients reported in the current SDR and that product is added to such reported number of in-center patients.
- (v) The sum from (3)(B)(iv) is divided by 3.2, and from the quotient is subtracted the facility's current number of certified stations as recorded in the current SDR and the number of pending new stations for which a certificate of need has been issued. The remainder is the number of stations needed.

(C) The facility may apply to expand to meet the need established in (3)(B)(v), up to a maximum of ten stations.

*[NOTE: "Rounding" to the nearest whole number is allowed only in Step 1(C), Step 2(C) and Step 3(B)(v). In these instances, fractions of 0.5000 or greater shall be rounded to the next highest whole number.]*

Unless specific “adjusted need determinations” are recommended by the North Carolina State Health Coordinating Council, an application for a certificate of need for additional dialysis stations can be considered consistent with the need determinations of this Plan only if it demonstrates a need by utilizing one of the methods of determining need outlined in this chapter.

**Timeline**

The schedule for publication of the North Carolina Semiannual Dialysis Reports and for receipt of certificate of need applications based on each issue of that report in shall be as follows:

<u>Data for</u> <u>Period Ending</u>	<u>Due Dates for</u> <u>SEKC Report</u>	<u>Publication</u> <u>of SDR</u>	<u>Application Due Dates</u> <u>for CON Applications</u>	<u>Beginning</u> <u>Review Dates</u>
<b>June 30, 2009</b> <b>Dec. 31, 2009</b>	<b>Nov. 9, 2009</b> <b>May 10, 2010</b>	<b>January 4, 2010</b> <b>July 1, 2010</b>	<b>March 15, 2010</b> <b>September 15, 2010</b>	<b>April 1, 2010</b> <b>October 1, 2010</b>

Please be advised that 5:30 p.m. on the specified Application Due Date is the filing deadline for any certificate of need application in response to these dialysis reports. The filing deadline is absolute.

**CHAPTER 4  
STATEMENT OF POLICIES -- Dialysis Excerpts Only**

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The only remaining dialysis policy appears on page 32 of the 2009 State Medical Facilities Plan. Staff has received no comments or petitions regarding the dialysis policy. The Agency recommends no changes to ESRD-2 for the Proposed 2010 Plan.

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**POLICIES RELATED TO END-STAGE RENAL DISEASE  
DIALYSIS SERVICES (ESRD)**

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**POLICY ESRD-1: AVAILABILITY OF DIALYSIS CARE**

*This former policy was edited and moved to the narrative of the Dialysis Chapter in the 1998 Plan.*

**POLICY ESRD-2: RELOCATION OF DIALYSIS STATIONS**

Relocations of existing dialysis stations are allowed only within the host county and to contiguous counties currently served by the facility. Certificate of need applicants proposing to relocate dialysis stations to contiguous counties shall:

- (A) demonstrate that the proposal shall not result in a deficit in the number of dialysis stations in the county that would be losing stations as a result of the proposed project, as reflected in the most recent Dialysis Report, and
- (B) demonstrate that the proposal shall not result in a surplus of dialysis stations in the county that would gain stations as a result of the proposed project, as reflected in the most recent Dialysis Report.