
CHAPTER 14

END-STAGE RENAL DISEASE DIALYSIS FACILITIES

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 ~~“July 2012 January 2013~~ North Carolina Semiannual Dialysis Report,” there were ~~179 182~~ 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 ~~4,210 4,266~~ dialysis stations. Certificates of need had been issued for an additional ~~187 200~~ dialysis stations, but the stations were not yet certified. Another ~~64 43~~ 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 zero to 14.

~~For the January 2013 North Carolina Semiannual Dialysis Report, Utilization~~ utilization data ~~are were~~ based on reported numbers of patients obtained from the Southeastern Kidney Council and the Mid-Atlantic Renal Coalition. Of the ~~177 178~~ certified facilities operational on ~~December 31, 2011 June 30, 2012~~, ~~68 75~~ were at or above 80 percent utilization (*i.e., operating with at least 3.2 patients per station*).

Changes from the Previous Plan

~~One substantive change has been adopted for the dialysis need methodology in the 2013 State Medical Facilities Plan. In response to a petition, the State Health Coordinating Council (SHCC) has removed Veteran’s Administration (VA) patients receiving dialysis treatments at VA dialysis clinics from the patient data by county, which is used to project County Need. Dialysis facilities operated by the VA are not regulated by Certificate of Need. Removing these patients from the County Need projections will avoid potential duplication of services for individuals who have access to treatment through the VA based on military service that are not available to the general public.~~

~~Veterans receiving dialysis services in non-VA dialysis facilities will continue to be included in the data by county of patient origin, which is used to project need for additional dialysis stations in community-based dialysis facilities that are regulated by Certificate of Need.~~

Due to recent changes in how the Centers for Medicare & Medicaid Services (CMS) and the End-Stage Renal Disease (ESRD) Networks are collecting and reporting dialysis data, Long-Term and Behavioral Health Committee (LTBH) members and the SHCC approved ~~an interim measure based on historical utilization patterns to project a three-year trend line providing an average for in-center and in-home dialysis patients until new reports can be developed.~~ a change in how data are collected. Beginning with the July 2013 North Carolina Semiannual Dialysis Report, utilization data were submitted by certified dialysis providers to the North Carolina Department of Health and Human Services, Division of Health Services Regulation. ~~(Note: In doing so there will be the inability to extract the VA patients receiving dialysis from VA dialysis clinics from the patient data report by county.)~~

No other changes in the dialysis policy or in the dialysis need methodology have been ~~incorporated into~~ recommended for the North Carolina ~~Proposed 2014~~ 2013 State Medical Facilities Plan. Dates have been advanced by one year, as needed to represent the time period for the ~~2013~~ 2014 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 Branch 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 Branch 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 Multicounty Planning Area and the Avery-Mitchell-Yancey Multicounty 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 Branch.
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 percent or greater. Any facility at 80 percent utilization or greater may apply to expand.
7. Facilities reporting no patients ~~through the Southeastern Kidney Council~~ to the Division of Health Service Regulation, Medical Facilities Planning

Branch for four consecutive Semiannual Dialysis Reports 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 and
 - 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 Acute and Home Care 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, 2012 2013 and as of December 31, 2012 2013 shall be provided by End-Stage Renal Disease providers operating certified dialysis facilities to the Division of Health Service Regulation, Medical Facilities Planning Branch. ~~the Centers for Medicare & Medicaid Services (CMS) through the Southeastern Kidney Council, Inc. (SEKC) and the Mid-Atlantic Renal Coalition, Inc. Data by county of patient origin provided through the SEKC will exclude patients receiving services at dialysis facilities operated by the Veterans Administration that are not regulated by Certificate of Need.~~

Method for Projecting New Dialysis Station Need

The Medical Facilities Planning Branch 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, 2012 2013 for the "January 2013 2014 SDR" and as of December 31, 2012 2013 for the "July 2013 2014 SDR." A new five-year trend line will be established in the "July 2012 2013 SDR" based on ~~validated~~ data as reported to the Division of Health Service

Regulation, Medical Facilities Planning Branch ~~CMS~~ for the time period ending December 31, ~~2012~~ 2013. Need for new dialysis stations shall be determined as follows:

1. County Need *(for the January ~~2013~~ 2014 SDR – Using the trend line ending with ~~12/31/11~~ 12/31/12 data)*
 - A. The average annual rate (percent) of change in total number of dialysis patients resident in each county from the end of ~~2007~~ 2008 to the end of ~~2011~~ 2012 is multiplied by the county's June 30, ~~2012~~ 2013 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, ~~2013~~ 2014 patients.
 - B. The percent of each county's total patients who were home dialysis patients on June 30, ~~2012~~ 2013 is multiplied by the county's projected total June 30, ~~2013~~ 2014 patients, and the product is subtracted from the county's projected total June 30, ~~2013~~ 2014 patients. The remainder is the county's projected June 30, ~~2013~~ 2014 in-center dialysis patients.
 - C. The projected number of each county's June 30, ~~2013~~ 2014 in-center patients is divided by 3.2. The quotient is the projection of the county's June 30, ~~2013~~ 2014 in-center dialysis stations.
 - D. From each county's projected number of June 30, ~~2013~~ 2014 in-center stations is subtracted the county's number of stations certified for Medicare, certificate of need-approved and awaiting certification, awaiting resolution of certificate of need appeals, and the number represented by need determinations in previous State Medical Facilities Plans or Semiannual Dialysis Reports for which certificate of need decisions have not been made. The remainder is the county's June 30, ~~2013~~ 2014 projected station surplus or deficit.
 - E. If a county's June 30, ~~2013~~ 2014 projected station deficit is 10 or greater and the January SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the June 30, ~~2013~~ 2014 county station need determination is the same as the June 30, ~~2013~~ 2014 projected station deficit. If a county's June 30, ~~2013~~ 2014 projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80 percent, the county's June 30, ~~2013~~ 2014 station need determination is zero.
2. County Need *(for the July ~~2013~~ 2014 SDR – Using a new trend line based on ~~12/31/2012~~ 12/31/2013 data)*

- A. The average annual rate (percent) of change in total number of dialysis patients resident in each county from the end of ~~2008~~ 2009 to the end of ~~2012~~ 2013 is multiplied by the county's December 31, ~~2012~~ 2013 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, 2013 patients.
- B. The percent of each county's total patients who were home dialysis patients on December 31, ~~2012~~ 2013 is multiplied by the county's projected total December 31, ~~2013~~ 2014 patients, and the product is subtracted from the county's projected total December 31, ~~2013~~ 2014 patients. The remainder is the county's projected December 31, ~~2013~~ 2014 in-center dialysis patients.
- C. The projected number of each county's December 31, ~~2013~~ 2014 in-center patients is divided by 3.2. The quotient is the projection of the county's December 31, ~~2013~~ 2014 in-center dialysis stations.
- D. From each county's projected number of December 31, ~~2013~~ 2014 in-center stations is subtracted the county's number of stations certified for Medicare, certificate of need-approved and awaiting certification, awaiting resolution of certificate of need appeals, and the number represented by need determinations in previous State Medical Facilities Plans or Semiannual Dialysis Reports for which certificate of need decisions have not been made. The remainder is the county's December 31, ~~2013~~ 2014 projected station surplus or deficit.
- E. If a county's December 31, ~~2013~~ 2014 projected station deficit is 10 or greater and the July SDR shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, ~~2013~~ 2014 county station need determination is the same as the December 31, ~~2013~~ 2014 projected station deficit. If a county's December 31, ~~2013~~ 2014 projected station deficit is less than 10 or if the utilization of any dialysis facility in the county is less than 80 percent, the county's December 31, ~~2013~~ 2014 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 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 (SDR₁) is subtracted from the number of in-center dialysis patients reported in the current SDR (SDR₂). The difference is multiplied by 2 to project the net in-center change for one year. Divide the projected net in-center change for the year by the number of in-center patients from SDR₁ 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, ~~2012~~ 2013 until December 31, ~~2012~~ 2013*) for the January 2, ~~2013~~ 2014 SDR and by 12 (*the number of months from December 31, ~~2012~~ 2013 until December 31, ~~2013~~ 2014*) for the July 1, ~~2013~~ 2014 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. The facility may apply to expand to meet the need established in 3.B.v, up to a maximum of 10 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 higher 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.

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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 ~~2013~~ 2014 shall be as follows:

Data for Period Ending	Publication of SDR	Application Due Dates for CON Applications	Beginning Review Dates
June 30, 2012 <u>2013</u>	January 2, 2013 <u>2014</u>	March 15, 2013 <u>17, 2014</u>	April 1, 2013 <u>2014</u>
Dec. 31, 2012 <u>2013</u>	July 1, 2013 <u>2014</u>	September 16, 2013 <u>15, 2014</u>	October 1, 2013 <u>2014</u>

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.

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