

UPDATED 5/2/2019:

- **Removal/correction of text regarding training stations.**
- **Removal of text in Basic Principle 1 that refers to the number of patients per station.**
- **Clarification that a “new” facility will have only one opportunity to apply for new stations.**
- **Addition of table and column references to the methodology steps.**
- **A few other miscellaneous minor corrections.**

Notes Regarding Edits to Chapter 9 (ESRD)

- The blue text indicates new text or text moved from another part of the old Chapter 14.
- If you compare this chapter to the old Chapter 14, you will notice that a lot of the text in the Basic Principles section has been removed. This was based on an internal review of the relevance of the principles. We did not present these suggested changes at any ESRD Interested Parties meeting. In some cases, the principles are far outside the scope of the SMFP/SHCC. In other cases, they are covered more generally in Chapter 1 of the SMFP.
- We presented the standard county and facility need methodologies at one of the ESRD Interested Parties meeting. I also attached these methodologies to the report I presented at the April Committee meeting. I have reformatted these sections of the document, but the methodologies have not changed. However...
- We added a condition to the facility need methodology that allows new facilities to add stations before they would normally be able to do so under the standard methodology.
- The Committee will have the opportunity to discuss this chapter at the meeting next week. If the Committee approves the chapter (as is or with changes), it will be forwarded to the SHCC for consideration at the May 29 meeting. Whatever is approved by the SHCC will appear in the Proposed 2020 SMFP.
- The public (including the dialysis providers) will have the opportunity to submit written comments during the public comment period in July.

CHAPTER 9

END-STAGE RENAL DISEASE DIALYSIS FACILITIES

Introduction

End-stage renal disease dialysis (ESRD) facilities (also known as kidney disease treatment centers) provide dialysis services, which is defined in 10A NCAC 14C .2201(5) as “the artificially aided process of transferring body wastes from a person’s blood to a dialysis fluid to permit discharge of the wastes from the body.” There are two types of dialysis: hemodialysis and peritoneal dialysis. Hemodialysis is the form of dialysis in which the blood is circulated outside the body through an apparatus which permits transfer of waste through synthetic membranes. Peritoneal dialysis means the form of dialysis in which a dialysis fluid is introduced into the person’s peritoneal cavity and is subsequently withdrawn. Peritoneal dialysis is performed in the patient’s home. Hemodialysis can be performed in the patient’s home (home hemodialysis) or in the ESRD facility (in-center hemodialysis).

Definitions

For the county need methodology, the service area is the county in which the dialysis station is located. Each county comprises a service area except: Cherokee, Clay and Graham Counties form a multi-county service area; and Avery, Mitchell, and Yancey Counties form a multi-county service area.

An “in-center” patient receives dialysis services at the ESRD facility only.

A “home” patient receives hemodialysis or peritoneal dialysis in his or her home only.

ESRD facilities report utilization data once each year on December 31. The “current” reporting date for this SMFP is December 31, 2018.

“Utilization” is the number of in-center patients served by the facility during the last week of December.

The “projection” date is one year beyond the current reporting date. The projection date for this SMFP is December 31, 2019.

The “past five reporting dates” are December 31 in 2014, 2015, 2016, 2017, and 2018.

Changes from the Previous Plan

The Semiannual Dialysis Report (SDR) will not be prepared after the release of the July 2019 SDR. Beginning with the Proposed 2020 State Medical Facilities Plan (SMFP), the county and facility need methodologies are fully incorporated into the annual healthcare planning process. In addition, ESRD facilities are now under the purview of the Acute Care Services Committee of the State Health Coordinating Council. As such, the previous Chapter 14 of the SMFP (End-Stage Renal Disease Dialysis Facilities) has moved to the Acute Care Services section of the SMFP and is now Chapter 9. Finally, the chapter has had technical edits as well as substantive edits to reflect these changes.

Basic Principles

1. New facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care.
2. As a means of making ESRD services more accessible to patients, one goal of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the facility. Therefore,

end-stage renal disease treatment should be available within 30 miles from the patients' homes. In areas where it is apparent that patients currently travel more than 30 miles for in-center dialysis, proposed new facilities that would serve patients who are farthest away from operational or approved facilities should receive favorable consideration.

3. The North Carolina State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for: home training and backup for facility-based patients suitable for home dialysis or in a facility that is a reasonable distance from the patient's residence; ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules; and services in rural areas.

Assumptions of the Methodology

1. The need determination methodologies exclude home patients.
2. Facilities may have at least one dialysis station dedicated to training of home dialysis patients. If so, these stations are included in the planning inventory.
3. Under the facility need methodology, any facility at 75 percent utilization or greater as of the current reporting date may apply to add dialysis stations.
4. Facilities that are eligible to add stations based on the facility need methodology may add the number of stations calculated by the methodology, up to a maximum of 20 stations in a single calendar year.
5. Facilities certified and in operation at least 9 but less than 21 months do not have a need determination in the SMFP. Rather, they may apply to add stations based on Condition 1 in the Facility Need Methodology.

Data Sources

Data on the current number of dialysis facilities and stations comes from the Healthcare Planning and 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. ESRD providers that operate certified dialysis facilities report data on the number of patients served to the Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section.

Application of the Methodologies

ESRD services have two methodologies: the county need methodology projects need for the county; the facility need methodology projects need for a specific facility. When a county need determination exists, any qualified applicant may apply to add stations in an existing facility or apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations.

County Need Determination Methodology (Table 9C)

- Step 1: Multiply the average annual change in the total number of dialysis patients resident in each county for the past five reporting dates (Column G) by the county's total number of patients for the current reporting date (Column F).
- Step 2: Add the result of Step 1 to the county's total number of patients for the current reporting date (Column F). The sum is the county's projected total number of patients (Column H).

- Step 3: Multiply the percentage of each county's total patients who were home dialysis patients (*Column I*) on the current reporting date (*Column J*) by the county's projected total patients as of the projection date (*Column H*). Subtract the product (*Column K*) from the county's projected total patients. The remainder is the county's projected in-center dialysis patients (*Column L*).
- Step 4: Divide the result of Step 3 by 3.2. The quotient is the projected number of in-center dialysis stations needed in the county (*Column M*).
- Step 5: Subtract from the result of Step 4 (*Column M*) the county's number of stations certified for Medicare, stations that are certificate of need-approved and awaiting certification, stations awaiting resolution of certificate of need appeals, and the number represented by need determinations in previous State Medical Facilities Plans for which certificate of need decisions have not been made (*Column N*). The remainder is the county's projected station surplus or deficit (*Column O*). Round fractions of 0.5 or greater to the next highest whole number.
- Step 6: If the result of Step 5 is 10 or greater and the SMFP shows that utilization of each dialysis facility in the county is 80 percent or greater, the county station need determination is the same as the projected station deficit (*Column P*). If a county's 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 has no need for additional stations. When a county has a need determination, applicants may apply for any number of stations up to and including the number of stations in the need determination.

Facility Need Determination Methodology

A dialysis facility located in a county that has no county need determination in the current SMFP may apply for additional stations under one of the two following conditions.

Condition 1: Pertains to “new” facilities.

- a. “New” facilities are defined as those facilities certified and in operation less than 21 months as of the “data cut-off date” for the current SMFP. This date is the last date on which the Agency updates data before publication of the current SMFP; the date is listed on the inside cover page of the SMFP. The number of days in a month is calculated as 365.25/12. (The “data cut-off date” occurs during the first week in October, but the actual date varies by year.) Facilities meeting this definition will be identified as such in Table 9B of the SMFP. New facilities may be eligible to apply to add stations in one Category D.1 certificate of need review cycle. That is, a new facility may apply to add stations in any Category D.1 review cycle, but it can apply only once during the period that it is defined as a new facility.
- b. The facility’s “current” reported utilization must be at least 3.0 patients per station in a given week. For purposes of Condition 1 only, “current” means in-center utilization as of a reporting date no more than 90 days before the date the certificate of need application is submitted.
- c. If the facility meets Condition 1.a and 1.b, use the following definitions and calculations to determine the number of stations needed:
 - i. Use the “current” and “previous” reporting dates to calculate the facility’s growth in utilization. For purposes of Condition 1 only, “previous” means in-center utilization as of a reporting date six months prior to the “current” reporting date.

- ii. Subtract the facility's number of in-center dialysis patients on the previous reporting date from the facility's number of in-center dialysis patients on the current reporting date. The difference is the net in-center change for six months.
 - iii. Divide the result of Condition 1.c.ii by the number of in-center patients from the previous reporting date. Then multiply that result by 2 to determine the projected annual growth rate.
 - iv. Multiply the result from Condition 1.c.iii by the facility's number of in-center patients as of the current reporting date.
 - v. Add the result from Condition 1.c.iv to the number of in-center patients as of the current reporting date.
 - vi. Divide the result of Condition 1.c.v by 2.8.
 - vii. Subtract the sum of (a) the facility's number of stations as of the current reporting date and (b) the number of pending new stations for which a certificate of need application has been approved or is under review from the result of Condition 1.c.vi. The remainder is the number of stations needed. Round fractions of 0.5 or greater to the next highest whole number.
- d. The facility may apply for any number of stations up to the number calculated in Condition 1.3.vii, up to a maximum of 10 stations. The applicant must demonstrate the need for the number of stations applied for in the CON application.

Condition 2: Pertains to facilities certified and in operation at least 21 months as of the date of publication of the SMFP (*Table 9B*).

- a. A facility may add stations if its utilization reported in the current SMFP is at least 75% (3.0 patients per station per week or greater), calculated as: $(((\text{Column L}/\text{Column K})/4) = \text{Column M}]$.
- b. If the facility's utilization reported in the current SMFP meets Condition 2.a, use the following calculations to determine the number of stations needed:
 - i. Subtract the facility's number of in-center dialysis patients reported in the previous SMFP from the number of in-center dialysis patients reported in the current SMFP (*Column L*). The difference is the net in-center change for one year. For the 2020 SMFP and Proposed 2020 SMFP only, use Table B in the July 2018 SDR rather than the previous SMFP to obtain the number of in-center dialysis patients for the previous reporting year.
 - ii. Divide the result of Condition 2.b.i by the number of in-center patients from the previous SMFP to determine the projected annual growth rate.
 - iii. Multiply the result from Condition 2.b.ii by the facility's number of in-center patients reported in the current SMFP (*Column L*).
 - iv. Add the result of Condition 2.b.iii to the number of in-center patients reported in the current SMFP.

- v. Divide the result of Condition 2.b.iv by 2.8.
 - vi. Subtract the total stations recorded in the current SMFP (*Column J*) from the result of Condition 2.b.v. The remainder is the number of stations needed (*Column N*). Round fractions of 0.5 or greater to the next highest whole number.
- c. The facility may apply to add stations to meet the need calculated in Condition 2.b.vi, up to a maximum of 20 stations. When a facility has a need determination, applicants may apply to add any number of stations up to and including the number of stations in the need determination. However, applicants must demonstrate the need for the number of stations applied for in the CON application. When a facility has a need determination, the applicant may apply to add stations up to three times per calendar year, but the total stations applied for in a single calendar year cannot exceed the total number of stations in the facility's need determination, as calculated in Condition 2.b.vi.