

Acute Care Services Committee
Agency Response
Summer 2019 Comments Regarding the ESRD Facility Need Methodology

Comments and Oral Remarks

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The Proposed 2020 SMFP contained revised need determination methodologies for End Stage Renal Disease (ESRD) dialysis facilities. The Summer of 2019 is the first opportunity for the public to comment on these revisions.

Background

The Acute Care Services (ACS) Committee held a series of Interested Parties meetings beginning in April 2018. The impetus for the meetings was the need to fully incorporate the ESRD methodologies into the SMFP to ensure proper review by the SHCC, public comment, and review by the Governor. Interested Parties meetings were held on April 13, 2018, November 14, 2018, January 16, 2019, and February 13, 2019.

Two need methodologies exist for ESRD services, a county methodology and a facility-specific methodology. The meetings involved discussion of the facility need methodology and options for the transition. The Agency developed a modeling tool to estimate how the facility need methodology could be adjusted to accommodate an annual data reporting period, as required for full incorporation into the SMFP. The county need methodology was not adjusted, except to account for annual data reporting.

The Agency prepared a report for the April 9, 2019 meeting of the ACS Committee. It discussed adjustments to the methodology as well as a policy approach. At this meeting, the Committee voted to adopt the methodology. The SHCC approved the Committee's action at its May 29, 2019 meeting, and the Proposed 2020 SMFP reflects these decisions.

Some comments request changes to the certificate of need (CON) review schedule. Healthcare Planning does not provide input regarding the CON review schedule. Rather, CON reviews these comments and adjusts the schedule if warranted.

Agency Response to Comments

The comments regarding the methodology can be organized along three related themes: (1) rejection of the methodology in favor of a policy approach; (2) flaws in the methodology; and (3) nonresponsiveness of the methodology.

Rejection of the Methodology

The three major dialysis providers do not favor the methodology approved by the SHCC. Rather, they favor a policy approach. The Agency is aware of these concerns, and they have been discussed in Interested Parties meetings and Acute Care Services Committee meetings.

One comment suggested delaying implementation until at least 2021 to address issues of concern. Another suggested a more detailed discussion of a policy approach by the Acute Care Services Committee.

Flaws in the Methodology

Comments from Wake Forest Baptist Health provide a detailed critique of the facility need methodology. They first assert that the methodology is flawed, in part, because the modeling tool cannot precisely project needs. We pointed out on several occasions that the modeling tool is a “tool” for examining potential changes to the methodology; it is not a precise duplication of what would occur with a revised methodology. Precise duplication is not possible, because of the need for inventory adjustments that are not feasible in a modeling tool. We must approximate the adjustments. The comments further note that the tool includes “both certified and CON-approved stations negating a reason to apply an inventory adjustment” (page 2(a)). In addition to certified and CON-approved stations, it is also necessary to account for stations for which a CON application has been received, but not yet approved. Therefore, it is necessary to apply an inventory adjustment in the estimates of projected need.

Page 4 of the comments compares “actual” need to the needs projected using the modeling tool to show that the annual need methodology performs poorly. The analysis defines the needs calculated in the Semiannual Dialysis Report (SDR) as the “actual” needs. All need determinations in the SDR and SMFP are projections; that is, they are mathematical estimates of need. Although the modeling tool uses the needs in the SDR as a base of comparison, it has always been clear that this figure is not a measure of actual needs. One could argue that the needs generated by the SDR have over-projected actual needs for some time. The evidence for this position is that dialysis facilities apply for roughly 30% of the needs generated by the SDR methodology. The need generated by the methodology is the maximum number of stations for which a facility may apply. CON applications require facilities to demonstrate that they can meet the CON performance standards. That is, facilities can only be approved for the number of stations that their data can show are needed. The logical conclusion is that the “actual” need, therefore, is the number of stations for which facilities apply, and not the number generated by the SDR.

In summary, the modeling tool is a “tool.” It is not the actual methodology. It is designed to be as close as possible. The movement of dialysis stations and patients between two data collection time points makes it impossible for any modeling tool to replicate a methodology precisely.

Nonresponsiveness of the Methodology

Comments generally express concern that the methodology cannot respond to the need for new dialysis stations in a timely manner. This concern has been expressed since the beginning of the process of adjusting the methodology for full incorporation into the SMFP. For the most part, information in the comments covers issues that the ACS committee has already considered. The annual methodology is likely to produce far more need determinations than facilities can prove are actually needed. This issue is addressed in the Agency Report on the petition from Fresenius Kidney Care. On the other hand, in our discussion paper of April 9, 2019, we acknowledged that the annual methodology may underestimate needs in some situations. Undoubtedly, the SDR methodology did so as well. All methodologies do, simply because they are projections.

For example, the methodology may not work well for all small facilities. To compensate for this potential problem, we propose to adjust the methodology to allow more flexibility for small facilities to apply for additional stations. Attachment 1 outlines the proposed text of this addition to the methodology.

Two comments included examples of facilities with significant growth between data submission and publication of the SMFP. The Agency has consistently recommended that entities file petitions to help alleviate such situations. The two facilities discussed in the comments from Wake Forest Baptist Health are excellent examples of situations in which a petition could have been filed. Given that this is the inaugural year for ESRD facilities to be fully incorporated into the SMFP, we recommend treating these comments as petitions. Attachment 2 outlines the analysis and recommendation for the Statesville Dialysis Center of Wake Forest University in Iredell County. Attachment 3 outlines the analysis and recommendation for the Mr. Airy Dialysis Center of Wake Forest University in Surry County.

Agency Recommendation:

The Agency's perspective has not changed from the report prepared for the April 9, 2019 ACS Committee meeting. The ACS Committee and the SHCC have both approved the changes to the reporting period and the revisions to the methodology as described in that report.

Based on the comments received by the August 8, 2019 deadline, the Agency makes four recommendations:

1. The Agency recommends that the methodology be implemented as described in the Proposed 2020 SMFP, with the adjustment for small facilities (Attachment 1).
2. The Agency recommends the inclusion of an adjusted need determination for up to 8 dialysis stations at the Statesville Dialysis Center of Wake Forest University in Iredell County in the 2020 SMFP (Attachment 2).
3. The Agency recommends the inclusion of an adjusted need determination for up to 8 dialysis stations at the Mt. Airy Dialysis Center of Wake Forest University in Surry County in the 2020 SMFP (Attachment 3).
4. The Agency recommends that for at least the first calendar year of implementation, Healthcare Planning will review data and comments received to determine whether adjustments are needed.

Attachment 1

The average number of stations per dialysis facility is 24. Facility size ranges from 4 to 58 stations. The standard deviation is 11. Therefore, it seems reasonable that a “small” facility may be defined as one that has 13 stations or fewer. The Proposed 2020 SMFP (Table 9B) contains 39 facilities that met this definition, accounting for about 20% of all dialysis facilities.

In small facilities, relatively small increases in the number of patients can lead to large increases in the utilization percentage. These changes can happen rather quickly. To account for issues that may arise with using annual data to project need in small facilities, the Agency proposes to adjust Condition 1 of the facility need methodology in Chapter 9 of the 2020 SMFP. This adjustment allows small facilities to use updated data in their CON applications.

Condition 1: Pertains to “new” facilities and “small” facilities.

- a. “New” facilities are defined as those facilities certified and in operation at least nine but 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.

“Small” facilities are defined as those facilities with fewer than a total of 13 certified stations plus CON-approved stations and stations applied for as of the current reporting date for this SMFP.

The facility’s “current” reported utilization must be at least 3.0 patients per station per 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.

- b. If the facility meets Conditions 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 before 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.b.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.b.iii by the facility's number of in-center patients as of the current reporting date.
 - v. Add the result from Condition 1.b.iv to the number of in-center patients as of the current reporting date.
 - vi. Divide the result of Condition 1.b.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.b.vi. The remainder is the number of stations needed. Round fractions of 0.5 or greater to the next highest whole number.
- c. The facility may apply for any number of stations up to the number calculated in Condition 1.b.vii, up to a maximum of 10 stations per year.
- d. New facilities and small 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 (see Chapter 3). [A small facility may apply to add stations in any Category D.1 review cycle, but it can apply only once during a calendar year.](#)

Attachment 2

Wake Forest Baptist Health (WFBH) submitted comments illustrating rapid growth in the Statesville Dialysis Center (SDC) of Wake Forest University in Iredell County.

As of the December 31, 2018 reporting date, SDC had 75 patients. By July 19, 2019, SDC had 86 patients. This represents a growth from 69.4% utilization to 80% utilization in about six months. Using this growth period, need determination calculations for the standard facility need methodology are as follows:

Certified stations		27
Pending stations		0
In-center patients as of 12/31/18 (Time 1 [T1])		75
In-center patients as of 7/19/19 (Time 2 [T2])		86
Step	Description	Result
i	Subtract: number of patients at T2 minus number of patients at T1	11
ii	Divide projected net in-center change for 1 year by number of patients at T1	0.1467
iii	Multiply the result of Step ii by the number of in-center patients reported at T2 to obtain the growth rate	12.6162
iv	Add the result of Step iii to the number of in-center patients reported at T2	98.6162
v	Divide the result of Step iv by 2.8 patients per station	35.2190
vi	Subtract from the result of Step v the number of certified and pending stations to determine the number of stations needed	8

Attachment 3

Wake Forest Baptist Health (WFBH) submitted comments illustrating rapid growth in the Mt. Airy Dialysis Center (MADC) of Wake Forest University in Surry County.

As of the December 31, 2018 reporting date, SDC had 80 patients. By June 30, 2019, MADC had 89 patients. This represents a growth from 74.1% utilization to 82.4% utilization in six months. Using this growth period, need determination calculations for the standard facility need methodology are as follows:

Certified stations		27
Pending stations		0
In-center patients as of 12/31/18 (Time 1 [T1])		80
In-center patients as of 7/19/19 (Time 2 [T2])		89
Step	Description	Result
i	Subtract: number of patients at T2 minus number of patients at T1	9
ii	Divide projected net in-center change for 1 year by number of patients at T1	0.1125
iii	Multiply the result of Step ii by the number of in-center patients reported at T2 to obtain the growth rate	10.0125
iv	Add the result of Step iii to the number of in-center patients reported at T2	99.0125
v	Divide the result of Step iv by 2.8 patients per station	35.3616
vi	Subtract from the result of Step v the number of certified and pending stations to determine the number of stations needed	8