

**Petition to the State Health Coordinating Council  
For Adjusted Need Determination Two Additional**

**PETITIONER**

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**STATEMENT OF REQUESTED ADJUSTMENT**

The proposed 2020 State Medical Facilities Plan (SMFP) currently indicates a need determination of zero (0) dialysis stations at the following five DaVita facilities that report utilization of 80% or greater.

County	Facility Identification Number	Provider Number	Facility	City	Certified Stations 12/31/2018	Number** In-Center Patients 12/31/2018	Utilization by Percent 12/31/2018	Facility Station Need Determination
Mecklenburg	001554	34-2627	Charlotte East Dialysis	Charlotte	34	109	80.15%	0
Alamance	140092	34-2709	Alamance County Dialysis	Graham	10	36	90.00%	0
Mecklenburg	130490	34-2707	Huntersville Dialysis	Huntersville	14	52	92.86%	0
Alamance	100785	34-2686	North Burlington Dialysis	Burlington	16	62	96.88%	0
Alamance	956036	34-2567	Burlington Dialysis	Burlington	16	65	101.56%	0

The petitioner requests that the need determination for these facilities be adjusted pursuant to a Policy ESRD-3, where Policy ESRD-3 is:

Policy ESRD-3: Addition of Dialysis Stations Based on Facility Need for facilities in operation at least 21 months as of the data cut-off date for the current SMFP

A kidney disease treatment center (facility) may submit a certificate of need (CON) application no more than three times in one calendar year pursuant to the review schedule in Chapter 3 of the SMFP. A facility qualifies to add stations if:

1. Current facility utilization reported in the CON application is 80% or greater (i.e., 3.2 patients per station per week; “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.); and
2. The facility’s growth rate demonstrates a deficit of at least one station, based on the utilization data in Form C of the CON application.

The calculated station deficit is the maximum number of stations for which a facility can apply in a single application. No facility may be approved to add more than a total of 20 stations in any calendar year.

## REASONS FOR THE REQUESTED ADJUSTMENT

The draft 2020 SMFP provides a need determination for each clinic based on December 31, 2018 census data. However, the Agency prepared a discussion paper for the Acute Care Services Committee for its April 9<sup>th</sup> meeting and noted several issues that the updated **facility need methodology does not address** (emphasis added), specifically as it relates to the issue of timely station development:

*We examined several other related factors, based on results of model development and concerns expressed in the Interested Parties meetings:*

- **Number of stations in the facility.** *Small facilities may have more difficulty generating sufficient utilization on an annual versus semiannual basis.*
- **Facilities in rural areas.** *These facilities tend to be smaller than average. If they fail to generate a need under an annual methodology, it may be more detrimental to patients due to the limited dialysis options in the area. The average facility size is 24 stations, but facilities in rural areas do not tend to exceed 15 stations.*
- **Growth.** *A facility may have had a larger than usual growth rate over a single time period. An annual methodology may not produce a sufficient number of stations when they are needed.<sup>1</sup>*

The facility need methodology does not address these issues. In the event that any of the five facilities identified fall into one of the three “gaps” of the methodology, applying the proposed policy provides a remedy that allows a facility to address the needs of its patient population in a timely manner.

## ADVERSE IMPACTS IF THE ADJUSTMENT IS NOT MADE

Without an adjustment, these facilities will have no opportunity to apply for additional stations throughout the entirety of 2020. As noted above, the facility need methodology falls short with regard to ensuring that some facilities (i.e., small facilities, rural facilities, and facilities with growth that isn’t adequately captured in the new annual methodology). The utilization at these facilities is already at a level that makes them eligible to expand. Should any of these facilities experience an increase in utilization that cannot be addressed in a timely manner, it may cause an undue burden on the facility and its patients as they wait until the 2021 SMFP is published. Those patients who want to choose one of these DaVita facilities would have a third shift as their only option of dialyzing at DaVita facility or even no option at all to choose one of these DaVita facilities if the patient population maxed out the facility’s capacity because of maintaining the status quo. A third shift is inconvenient for patients and a facility at maximum capacity eliminates patient choice.

## ALTERNATIVES CONSIDERED BUT FOUND NOT FEASIBLE

DaVita considered the following alternative:

1. **Do Nothing.** Should any of these facilities experience an increase in utilization that cannot be addressed in a timely manner, it may cause an undue burden on the facility and its patients as they wait until the 2021 SMFP is published.

## PROPOSED ADJUSTMENT WILL NOT RESULT IN UNNECESSARY DUPLICATION

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<sup>1</sup> [https://www2.ncdhhs.gov/dhsr/mfp/pdf/2019/acsc/0402\\_esrd\\_discussionpaper.pdf](https://www2.ncdhhs.gov/dhsr/mfp/pdf/2019/acsc/0402_esrd_discussionpaper.pdf) (Agency Discussion Paper, Prepared for Acute Care Services Committee, April 9, 2019)

Adjusting the facility need based on a policy would not result in unnecessary duplication. The adjustment would only affect a single facility, based on its utilization, and provide *an opportunity*, if all the policy's criteria were met, to add stations at that specific facility. It ultimately serves to meet the needs of the facility's population of patients referred by the facility's admitting nephrologists. Any addition of stations, therefore, would serve to increase capacity rather than duplicate any existing or approved services in the facility's service area. When providers apply for station expansions and new centers, we must meet the performance standard of 80% station utilization, or 3.2 patients per station, by the end of operating year one (10A NCAC 14C .2203). The construct needed to ensure dialysis providers do not build more facilities and add more stations than needed, thereby increasing the cost of dialysis care, already exists through the this performance standard.

## **CONSISTENCY WITH BASIC SMFP PRINCIPLES**

### SAFETY AND QUALITY

The requested adjustment is consistent with principle of safety and quality. As noted in the SMFP "[c]itizens of North Carolina rightfully expect health services to be safe and efficient." Providing an opportunity, via policy, for these facilities to apply for stations when they are needed would not negatively impact safety, clinical outcomes, or satisfaction. Patient satisfaction would most likely be improved in a growing facility that is able to avoid third shifts by having the opportunity to apply for additional stations in a timely manner.

### ACCESS

The requested adjustment ensures equitable and timely access by allowing facilities that meet the criteria in the proposed policy to apply for additional stations, when they are needed.

### VALUE

Providing an opportunity for these facilities to apply to expand as soon as they identify a need rather than waiting until the next SMFP is published will allow for greater operational efficiency.

## **CONCLUSION**

Chapter Two of the North Carolina 2019 SMFP provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring and petitions requesting adjustments to need projections in the summer. The petitioner recognizes that its request to adjust the need projections for the five facilities identified via a policy change falls in both categories, and believes it is within the SHCC's purview to make the requested adjustments before the 2020 SMFP is finalized. Considering that the significant change of semiannual data reporting of data to annual reporting of data could have unintended consequences, approving this petition would provide a remedy to the identified shortcomings of the facility need methodology in the proposed plan which otherwise could negatively impact dialysis patients who rely on timely access to life-sustaining care.

## **ATTACHMENTS**

[https://www2.ncdhs.gov/dhsr/mfp/pdf/2019/acsc/0402\\_esrd\\_discussionpaper.pdf](https://www2.ncdhs.gov/dhsr/mfp/pdf/2019/acsc/0402_esrd_discussionpaper.pdf) (Agency Discussion Paper, Prepared for Acute Care Services Committee, April 9, 2019)

**Agency Discussion Paper**  
**End-Stage Renal Disease (ESRD) Dialysis Facilities**  
**Interested Parties Meetings, 2018-2019**  
**Healthcare Planning and Certificate of Need**

**Prepared for Acute Care Services Committee, April 9, 2019**

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### **Introduction**

The purpose of this report is to summarize the activities that have taken place regarding the transition of the Semiannual Dialysis Report (SDR) to full incorporation of ESRD into the State Medical Facilities Plan (SMFP). Interested Parties meetings were held on April 13, 2018, November 14, 2018, January 16, 2019 and February 13, 2019. The meetings involved discussion of the methodology and options for the transition. Unlike a workgroup that presents a formal recommendation to the SHCC, the Interested Parties meeting approach does not. Rather, the Agency submits this report to the Committee.

The options developed by Healthcare Planning were sensitive to the providers' concerns. We believe that either of the options discussed in this report can account for the growth rate in ESRD patients. Of course, we understand that the growth rate can vary considerably across individual facilities. Our analysis and model testing has shown that we can account for the age of the data. If the policy option is chosen instead of the methodology, those concerns would be moot.

### **Summary of Current Methodology**

ESRD has two separate methodologies – county and facility. The county need methodology uses a five-year trend line to project station utilization up to 12 months into the future. If all ESRD facilities in a county have at least 80% utilization and the deficit is at least 10 stations, the county has a need determination. If the SMFP has a county need determination then any qualified entity may apply to develop the stations needed. County need determinations are rare.

Under the facility need methodology, if the county need is zero and a facility reports at least 80% utilization, then that facility has a need determination. A subsequent calculation applies a growth rate to determine the number of additional stations needed (up to a maximum of 10 additional stations per facility). The ESRD facility need methodology is unique in that only the facility that generated the need is eligible to apply for additional stations. Unlike other health services in the SMFP, it is common for ESRD providers to submit CON applications for fewer than the number of stations in the need determination.

## Agency Discussion

To accomplish incorporation of the ESRD process into the SMFP, we prepared two options for the Acute Care Services Committee to consider. The first option presented is an adjustment to the existing methodologies. The second is a policy-based approach.

### Methodology

In general, we do not propose a redesign to either of the ESRD methodologies. Rather, we primarily have adjusted parameters to address the annual reporting period. Attachment A shows the edits to be made to the county methodology section of the chapter narrative to accommodate an annual reporting cycle. No further changes are necessary or recommended at this time. Attachment B shows the edits to be made to the facility methodology section of the chapter narrative to accommodate the annual reporting cycle, based on the parameters in the model developed by Healthcare Planning. Due to the transition from semiannual to annual data reporting, we created a modeling tool to show how an annual methodology can work. The tool also compares the facility-based needs generated between an annual and semiannual process.

The model projects dialysis station need based on annual data reporting. The modeling tool allows users to compare needs based on semiannually reported data to needs calculated using data reported annually.

We created two models that reflect data applicable to the 2018 SMFP. The first model (the “3 SDR” model) examines facility needs across three SDRs. The 3 SDR model uses the January 2017, July 2017, and January 2018 SDRs, which reflect data as of June 30, 2016, December 31, 2016, and June 30, 2017, respectively. For example, the June 30, 2016 data reporting point is a count of the number of individual patients served during the month of June. The second model (the “annual” model) adjusts the parameters for annual reporting so that the methodology produces at least as many needs as would be generated across three SDRs combined. The annual model uses data from December 31, 2016 for the 2018 SMFP. These reporting dates reflect the most current data available at the time of the analysis. This approach enables us to examine data that covers the complete age range of the data that would be used in the 2018 SMFP (i.e., data that is 12, 18, and 24 months old).

Preliminary analysis also tested other time points. Concern may exist that facilities may be more likely to have higher utilization in June rather than December, or vice versa. In some preliminary tests, the 3 SDR model used two June 30 and one December 31 data collection points, while others used one June 30 and two December 31 data collection points. Our analysis showed very similar results regardless of the three data collection points used.

In developing the model, we examined patterns of need determinations and CON applications. We also considered concerns raised by providers, such as the effect of the proposed model on rural counties and on small dialysis facilities. The final analysis shows that the model performed well overall.

The annual model for the facility need methodology does the following:

- *Uses an annual reporting period.* Data would be reported as of December 31 of each year.
- *Lowers utilization threshold for a need determination, from 80% to 75%.* Lowering the threshold helps account for the lack of a second data reporting period in the calendar year and for the age of the data at the time of a CON application. A lower threshold triggers needs sooner for a facility than the current threshold.
- *Lowers utilization criterion to determine the number of stations needed, from 80% to 70%.* Lowering this threshold increases the number of stations in the need determination, provided that the facility is at 75% utilization.
- *Doubles the maximum allowable facility need determination.* The maximum semiannual need is 10 stations. The annual model increases the maximum to 20.
- *Assumes that facilities applied for all prior needs (up to 10) in each SDR that showed a need.* It is not feasible for the modeling process to account for the number of stations applied for with total accuracy. Therefore, the model assumes that facilities applied for all of the stations that the current methodology showed they needed, even though it is common for facilities to apply for fewer or not apply at all. This assumption increases the planning inventory. The result is that the model may calculate a need that is lower than the actual need.

The following table summarizes the annual model and compares it to the 3 SDR model. It shows the model presented at the January 13, 2019 Interested Parties meeting. It is important to point out that we can adjust the parameters in the annual model (in “real time”) to examine other results.

Number of Facilities				Number of Stations Needed		
With needs in 3 SDRs	With needs in Annual model	3 SDRs=Yes Annual=No	3 SDRs=No Annual=Yes	3 SDRs	Annual	Difference (annual minus 3 SDRs)
98	108	12	22	890	893	4*

\* produced by subtraction of actual values, not the rounded numbers shown in the two preceding columns.

The first two columns show that 98 facilities had needs in the 3 SDR model, compared to 108 in the annual model. In 12 facilities, the 3 SDR model triggered needs for a total of 25 stations in facilities where the annual model did not show a need. On the other hand, in 22 facilities, the annual model triggered a need but the 3 SDR model did not. This result means that the annual model produced needs for 42 stations in the 22 facilities that would not have had a need across three SDRs. The annual model produced almost exactly the same number of needs as did the most recent 3 SDRs combined (893 compared to 890). Under the current facility methodology, a single SDR produces need for approximately 400-500 additional dialysis stations.

The modeling process assumes that facilities applied for all of the stations calculated as needed across 3 SDRs. Changing this assumption affects the needs for the 3 SDR model only, not the annual model. This figure produces an estimate of the number of stations to add to the calculations to account for approved new stations not yet developed. It is important to account for stations under development, but it is not feasible for the current calculations to include the exact data for all time points. We know that facilities often do not apply for all of the stations the SDR methodology produces. In fact, a preliminary analysis showed that facilities apply for about 25% of the stations that the current semiannual methodology produces. Therefore, this parameter will show a lower number of needs across 3 SDRs than if the model assumes that facilities applied for no new stations. The accurate number is between zero and 10, but it is not feasible to ascertain the exact number.

## **Policy**

In lieu of a formal methodology with need determinations published in the SMFP, it is possible to establish a mechanism to address facility needs via a policy that would appear in Chapter 4 of the SMFP. A policy would not rely on data reported annually. Rather, the facility applying for a CON would include current utilization figures in the application. The SMFP would include a new policy, but CON would also need to implement some changes to their processes. The example policy below includes terms (e.g., “current,” “growth rate”) that would need to be defined. The primary purpose of the example is to show the elements that would need to be in a policy. A policy might look like the following:

### Policy ESRD-3: Addition of Dialysis Stations Based on Facility Need

A kidney disease treatment center (facility) may submit a certificate of need (CON) application no more than three times in one calendar year pursuant to the review schedule in Chapter 3 of the SMFP. A facility qualifies to add stations if:

1. Current facility utilization reported in the CON application is 80% or greater (i.e., 3.2 patients per station per week); and
2. The facility’s growth rate demonstrates a deficit of at least one station, based on the utilization data in Form C of the CON application.

The calculated station deficit is the maximum number of stations for which a facility can apply in a single application. No facility may be approved to add more than a total of 20 stations in any calendar year.

A facility in operation less than 24 months (or another length to be determined) shall use the county utilization figures in Chapter 14 from the previous SMFP to calculate facility rate for purposes of the CON application. (The language in this element would need to be

altered for the first year the policy would be in effect, because the “previous” SMFP will not contain ESRD data.)

## **Outstanding Issues Related of the Facility Need Methodology**

***Limiting Applications Based on Projects in Development.*** It may be desirable to limit the number of new stations that can be approved for providers that have a “large” number of stations under development in the same county. (“Large” would need to be defined.) The rationale is that providers should not receive approval to develop additional stations until a large proportion of the outstanding stations have been certified.

***Maximum Number of Stations per Year.*** It is possible to limit a single facility to a maximum number of additional stations in a single calendar year. Currently, a facility can apply for up to 10 stations pursuant to each SDR. The annual model simply doubled this number to 20 for testing purposes. A methodology could have any other maximum, or allow facilities to apply for whatever number of stations the methodology calculates as needed.

***Number of Applications Dates per Year.*** Neither the methodology nor the policy approach assumes that a single facility can have only one opportunity per year to apply for a CON simply because facilities will submit data only once per year.

***Other Concerns.*** We examined several other related factors, based on results of model development and concerns expressed in the Interested Parties meetings:

- ***Number of stations in the facility.*** Small facilities may have more difficulty generating sufficient utilization on an annual versus semiannual basis.
- ***Facilities in rural areas.*** These facilities tend to be smaller than average. If they fail to generate a need under an annual methodology, it may be more detrimental to patients due to the limited dialysis options in the area. The average facility size is 24 stations, but facilities in rural areas do not tend to exceed 15 stations.
- ***Growth.*** A facility may have had a larger than usual growth rate over a single time period. An annual methodology may not produce a sufficient number of stations when they are needed.
- ***Relocation of Stations.*** It is common for providers to relocate stations both to existing facilities and to develop new facilities. When this occurs, it can affect growth rates and utilization for a limited time. The model does not explicitly address the effect of relocation on need determinations.



## Attachment A

### Edits to ESRD County Need Methodology Narrative for 2019 SMFP

- a. The average annual rate (percent) of change in total number of dialysis patients resident in each county from the end of 2013 to the end of 2017 is multiplied by the county's December 31, 2017 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, 2018 patients.
- b. The percent of each county's total patients who were home dialysis patients on December 31, 2017 is multiplied by the county's projected total December 31, 2018 patients, and the product is subtracted from the county's projected total December 31, 2018 patients. The remainder is the county's projected December 31, 2018 in-center dialysis patients.
- c. The projected number of each county's December 31, 2018 in-center patients is divided by 3.2. The quotient is the projection of the county's December 31, 2018 in-center dialysis stations.
- d. From each county's projected number of December 31, 2018 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 [previous](#) 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, 2019 projected station surplus or deficit. [Fractions of 0.500 or greater round to the next higher whole number.](#)
- e. If a county's December 31, 2018 projected station deficit is 10 or greater and the ~~July SDR~~ [2019 SMFP](#) shows that utilization of each dialysis facility in the county is 80 percent or greater, the December 31, 2018 county station need determination is the same as the December 31, 2018 projected station deficit. If a county's December 31, 2018 projected station deficit is 10 or greater and the ~~July SDR~~ [2019 SMFP](#) shows the county has no dialysis facility located in the county, then the December 31, 2018 county station need determination is the same as the December 31, 2018 projected station deficit. If a county's December 31, 2018 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, 2018 station need is zero.

(Note: This attachment is for illustration purposes only. The 2019 SMFP will not be revised.)

## Attachment B

### Edits to ESRD Facility Need Methodology narrative for 2019 SMFP

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~~ 3.0 patients per station or greater.
- b. Such need, calculated as follows, is reported in an application for a certificate of need:
  - ii. The facility's number of in-center dialysis patients reported in the previous ~~Dialysis Report (SDR<sub>1</sub>)~~ SMFP is subtracted from the number of in-center dialysis patients reported in the current ~~SDR (SDR<sub>2</sub>)~~ SMFP. 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 ~~SDR<sub>1</sub>~~ the previous SMFP to determine the projected annual growth rate.
  - ~~iii. The quotient from 3.b.i. is divided by 12.~~
  - iv. ~~The quotient from 3.b.ii. is multiplied by 6 (the number of months from June 30, 2018 until December 31, 2018) for the January 2, 2019 SDR and by 12 (the number of months from December 31, 2017 until December 31, 2018) for the July 1, 2019 SDR.~~
  - v. The ~~product~~ quotient from 3.b.~~iii.~~ i. is multiplied by the ~~number of the~~ facility's number of in-center patients reported in the current ~~SDR~~ SMFP and that product is added to such reported number of in-center patients.
  - iii. The sum from 3.b.~~iv.~~ ii. is divided by ~~3.2~~ 2.8, and from the quotient is subtracted the facility's current number of certified stations as recorded in the current ~~SDR~~ SMFP and the number of pending new stations for which a certificate of need application has been approved. The remainder is the number of stations needed. Fractions of 0.500 or greater round to the next higher whole number.
- c. The facility may apply to expand to meet the need established in 3.b.~~v.~~ iii., up to a maximum of ~~40~~ 20 stations.

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

(Note: This attachment is for illustration purposes only. The 2019 SMFP will not be revised.)