Petition to the State Health Coordinating Council
For Changes in ESRD Policies and Methodologies in the
2021 State Medical Facilities Plan

PETITIONER

DaVita, Inc. and its related dialysis facilities in North Carolina
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STATEMENT OF REQUESTED CHANGE

DaVita, Inc. and its related dialysis facilities in North Carolina respectfully petition the State Health Coordinating Council (SHCC) to adopt a policy for the addition of dialysis stations to existing or approved facilities, in lieu of a formal methodology with need determinations published in the SMFP.

Proposed 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; "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 applicant must demonstrate the need for the stations and satisfy the performance standards at 10A NCAC 14C .2203.

REASONS FOR THE CHANGE TO POLICY/METHODOLOGY

Background

Prior to 2020, End Stage Renal Disease (ESRD) data was reported twice a year in the Semiannual Data Report. The 2020 State Medical Facilities Plan (SMFP) is the first SMFP to fully incorporate ESRD data and marks a transition to annual data reporting. In transitioning to annual data reporting, it was necessary for the SCHCC to review and revise the methodologies for ESRD services.

Two need methodologies exist for End Stage Renal Disease (ESRD) services: a county methodology and a facility-specific methodology. The county need methodology was not adjusted, except to account for annual data reporting. The Acute Care Services (ACS) Committee, with support from the Agency and in collaboration with providers, spent a considerable amount of time discussing and analyzing possible adjustments to the methodology.

The need generated by the methodology is the ***maximum*** number of stations for which a facility may apply. The age of the ESRD data in the SMFP combined with the need generated by the methodology impose significant, and unnecessary, limits on ***timely*** dialysis station expansion. It was a concern raised repeatedly by providers and

physicians during the Summer Public Hearings in 2019 and noted by the Agency in a report to the ACS Committee:

> *"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."* (emphasis added).[1]

The Agency attempted to address this concern by twice modifying the revised methodology with an adjustment first, for "new" facilities and then for "small" facilities. The Agency recognized and acknowledged provider's concerns that the revised methodology might not work well for these two types of facilities. The revised methodology was accepted by the SHCC and implemented in the 2020 SMFP.

Review of available current data

Given available information recently submitted by all ESRD providers to the Agency, it is clear that this issue – ***the facility need methodology cannot respond to the need for new dialysis stations in a timely manner*** – has not been sufficiently addressed by the revision nor the additional modifications to the methodology.

On February 7, 2020, providers submitted patient census data to the Healthcare Planning Section which provided a snapshot of our in-center hemodialysis population as of December 31, 2019. This self-reported data will be used to calculate facility need determinations for the proposed 2021 SMFP. This census data shows the limitations of the facility need methodology, specifically as it relates to the issue of responding to the need for new dialysis stations in a timely manner.

The key data used to calculate the need determination in Table 9B of the 2020 SMFP is self-reported in-center hemodialysis patient census dated December 31, 2018. The need determination published for each facility in the 2020 SMFP serves as a determinative limit on the number of dialysis stations that facilities can apply to add throughout the year. Any facility with a need determination of zero (0) dialysis stations will have to wait until 2021 to have the opportunity to apply for additional stations, even if the current growth at that facility indicates additional dialysis stations are needed.

Unfortunately, there are 38 facilities currently in that situation. The census data from December 31, 2019 show enough growth since December 31, 2018 to indicate a need for additional stations in these 38 facilities, but because they have a need determination of zero dialysis stations in the 2020 SMFP they cannot apply for additional stations in 2020. Some of these facilities will qualify for an expansion because they fall into the "new" or "small" designation, but this still highlights the gaps created by the stated need methodology. There are an additional 42 facilities that have a facility need in the 2020 SMFP and that have experienced significant growth since December 31, 2018. Significant enough that they will still have a projected need for additional stations in the 2021 SMFP, even if they applied for all the stations in their projected need in the 2020 SMFP. This is further evidence that the limiting effect of the need determination produced by the methodology negatively impacts the ability of providers to sufficiently plan for adding stations **when they are needed**.

Based on the current methodology (75% utilization threshold) these facilities can demonstrate a need for additional stations as of December 31, 2019, but will not have an opportunity to apply for additional stations

[1] Agency Response to Summer 2019 Comments Regarding the ESRD Facility Need Methodology, p.3

until April 1, 2021 at the earliest. This delay between when a center shows a need and when that need may be filled will cause dialysis patients to be limited in their preferred choice of a dialysis center and/or shift, and unnecessarily limit the ability of providers and physicians to timely meet the needs of the patients to be served. Additionally, if the required utilization rate was raised to 80% - the threshold in place using the old SDR model - and applicants needed to prove projected utilization of 3.2 patients per station, 28 of the 38 facilities mentioned would still qualify to apply for additional stations based on their December 31, 2019 census.

Clearly, using data from 2018 to calculate a determinative limit to be used throughout 2020 creates too large of a gap for the methodology to cover. This leaves a significant number of facilities with no recourse as these facilities cannot add additional stations to meet an increased patient need until July 2021 at the earliest – a delay of 18 months. The table below illustrates this.

			CON Application Review Period (90 - 150 days)		
Application Due Date	**Category**	**Type of Application**	**CON Review Begins**	**90-day Application Review period ends**	**150-day Application Review period ends**
3/16/2021	D.1	Expansion via Facility Need	4/1/2021	6/30/2021	8/30/2021

It could be argued that the annual methodology may underestimate needs in some situations, as do most methodologies, given that they are projections, and this gap or lag in response time between an identified need for additional dialysis stations and the opportunity to apply for additional stations is an unavoidable function of this underestimation. The problem, though, is not the underestimation or overestimation of projected need – facilities can only apply for the number of stations they can prove are actually needed. The problem that this petition seeks to address is the concern that the methodology cannot respond to the need for new dialysis stations in a timely manner.

ADVERSE IMPACTS IF THE CHANGE IS NOT MADE

Without the proposed policy, it is clear that many patients and facilities will be negatively impacted. No amount of "right-sizing" the methodology to produce facility need determinations will change the fact that the limit set by that need determination prevents many facilities with a provable need from an opportunity to **apply** for additional stations for over a year to address that need. As noted above, the facility need methodology falls short. This will most likely cause an undue burden on the facility and its patients as they wait until the next 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 a 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***. As the available data shows, we know that right now there are facilities whose growth between December 31, 2018 and December 31, 2019 provides evidence that there is a need for additional stations. But they are constrained by a need determination of zero stations in the 2020 SMFP. This may cause an undue burden on the facility and its patients as they wait until the 2021 SMFP is published to have an opportunity to address this need. Doing nothing sets the stage for this same scenario to play out in 2021.

2. ***Submit Petitions for Adjusted Need.*** Submitting a petition in the summer of 2020 for an adjusted need determination in the 2021 SMFP does not address the issue of a methodology that cannot respond to the need for new dialysis stations in a timely manner.

The proposed policy is an ideal solution. The framework for demonstrating a need and meeting a projected need already exists and has worked well to allow providers to meet the needs of a growing patient population for many years. The proposed policy would ensure that the SMFP allows providers could continue to appropriately plan for growth in their facilities in a timely manner. Consider this assessment from the Agency's Discussion Paper to the Acute Care Services Committee on April 9, 2019: "The options developed by Healthcare Planning were sensitive to the providers' concerns…If the policy option is chosen instead of the methodology, those concerns would be moot."

PROPOSED ADJUSTMENT WILL NOT RESULT IN UNNECESSARY DUPLICATION

Adopting a policy to add stations based on facility need would not result in unnecessary duplication of services. The SMFP does not have a methodology to project need for additional services, equipment and technology in several other categories. A policy can just as effectively incorporate the necessary guardrails to ensure that facilities do note develop more stations that are needed by a facility. In fact, 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 in 10A NCAC 14C .2203. Thus performance standard requires applicants to prove a need by meeting a current utilization threshold and demonstrate that a projected population would meet a minimum utilization, with the additional stations, by operating year one. A policy would not override rule, maintaining the same mechanisms for preventing duplication. Additionally, a policy approach allows for the return to a higher utilization rate and projected utilization rate of 80%. These higher thresholds were used for many years, but in conjunction with data that was only six months old. Raising these utilization thresholds naturally restricts duplication by raising the standard for which providers may apply for expansion.

CONSISTENCY WITH BASIC SMFP PRINCIPLES

<u>SAFETY AND QUALITY</u>

The proposed policy 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.

Moving to a policy approach does not affect patient safety or quality of care. The proposed policy will allow facilities which are operating at higher utilization rates to apply for additional dialysis stations. This will ensure a sufficient number of stations are located at facilities where patients are referred by their attending nephrologist for dialysis.

<u>ACCESS</u>

The proposed policy 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.

<u>VALUE</u>

The proposed policy would allow facilities to apply to develop additional stations where they are needed in a timely manner. Allowing a facility to apply for additional stations based on current data would be much more

valuable to all concerned. Providing an opportunity for dialysis 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

As detailed in Chapter One of the North Carolina 2019 SMFP, "[t]he major objective of the Plan is to provide individuals, institutions, state and local government agencies, and community leadership with policies and projections of need to guide local planning for specific health care facilities and services." Considering that the significant change of semiannual data reporting of data to annual data reporting 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

Facility Need Determinations based on December 31, 2019 data compared to 2020 SMFP

https://info.ncdhhs.gov/dhsr/mfp/pdf/2019/acsc/0910_esrd_agencyresponse.pdf (Agency Response to Summer 2019 Comments Regarding the ESRD Facility Need Methodology, September, 17, 2019)

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)