Petition to the State Health Coordinating Council
For Changes in Methodologies in the
2024 State Medical Facilities Plan

PETITIONER
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STATEMENT OF REQUESTED CHANGES

DaVita respectfully petitions the State Health Coordinating Council (SHCC) to amend the Assumptions of the Methodology found in Chapter 9: END-STAGE RENAL DISEASE DIALYSIS FACILITIES as currently published in the 2023 SMFP. This petition includes the following proposed revisions and additions:

1. Amend the following definition to include the italicized language:

   - A ***home training facility*** is an ESRD dialysis facility dedicated exclusively to the training of hemodialysis or peritoneal dialysis patients to dialyze at home or at a location other than a kidney disease treatment center that provides in-center dialysis, as defined in G.S. § 131E-176(14e). A home training facility must be physically separate (i.e., may not have the same Facility Identification (FID) number) from a kidney disease treatment center *that provides in-center dialysis*.

2. Add the following definition:

   - The ***need planning inventory*** is the number of in-center dialysis stations used in county and facility need determination calculations and includes the number of in-center stations certified by the Centers for Medicare and Medicaid Services, in-center stations that have been approved by the Department of Health and Human Services, Division of Health Service Regulation, Healthcare Planning and Certificate of Need Section and awaiting certification, or new in-center stations for which a CON application is pending or awaiting resolution of CON appeals. Certified dialysis stations at home training facilities are excluded from the need planning inventory.

3. Revise Assumption 8 to read:

   8. When a CON application has been received to relocate stations to a home training facility, the stations to be relocated are included in both the county and facility need determination calculations. When the home training stations are certified, then they *are excluded from the need planning inventory, as well as both the county and facility need determination calculations, and are included in Table 9E: Inventory of Dialysis Home Training Facilities.*

4. Add the following to the Assumptions of Methodology:

   10. When a CON application has been received to develop new stations or to increase the number of stations at a home training facility, these proposed stations are excluded from the need planning inventory, as well as both the county and facility need determination calculations. These proposed stations are included in Table 9E: Inventory of Dialysis Home Training Facilities.

5. Add the following notes to the assumptions:

   a. **NOTE**: The county and facility need methodologies exclude stations at a home training facility that are used exclusively for home hemodialysis training and support services from the county and facility need determination calculations.

      Dialysis stations certified for use at home training facilities will only be used for home hemodialysis training and support services.

      Providers proposing to develop new dialysis stations at Home Training Facilities to be used exclusively for home hemodialysis training and support services must obtain a CON but may apply for a CON without regard to the need determinations in this chapter.

   b. Move the footnote[1] found at the end of Table 9A: Inventory of Dialysis Stations and Calculation of Utilization Rates to a Note to the assumptions and revise it to read:

      NOTE: Policy ESRD-3 (Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus) is a policy that came into effect in the 2021 SMFP. Certified outpatient dialysis stations that existed in two hospitals** as of the date of implementation of this policy were removed from the inventory and methodologies; these facilities are treated as though the stations were developed pursuant to this policy *and are included in Table 9F: Inventory of Stations in Kidney Disease Treatment Centers on a Hospital Campus.*

      ** North Carolina Baptist Hospital (34-2304) in Forsyth County;
      ** Carolinas Medical Center (34-2306) in Mecklenburg County

[1] 2023 SMFP, page 130: "** Policy ESRD-3 (Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus) is a policy in the 2021 SMFP. Certified outpatient dialysis stations that existed in hospitals as of the date of implementation of this policy were removed from the inventory and methodologies; these facilities are treated as though the stations were developed pursuant to this policy. The following facilities were removed from the inventory: North Carolina Baptist Hospital (34-2304) in Forsyth County and Carolinas Medical Center (34-2306) in Mecklenburg County."

6. Revise Table 9E: Inventory of Dialysis Home Training Facilities to include additional columns, so as to follow the same structure as Table 9A: Inventory of Dialysis Stations and Calculation of Utilization Rates. The proposed additions are columns F, G, and H below:

Table 9E: Inventory of Dialysis Home Training Facilities

A	B	C	D	E	F	G	H	I	J	K	L
					Home Training Stations						
County	Facility Identification Number	Provider Number	Facility	City	CON Issued/ Not Certified	CON Decision Rendered (Conditional Approval)	CON Decision Pending	CON Total	Certified Stations 12/31/2022	Home Hemodialysis Patients 12/31/2022	Peritoneal Dialysis Patients 12/31/2022

BACKRGOUND

DaVita serves more home dialysis patients than any other provider in the U.S. and growth of our peritoneal dialysis (PD) and home hemodialysis (HHD) programs nationally is five times the growth rate of in-center treatment options.[2] A variety of factors, including policy shifts, technology innovations and response to the challenges of COVID-19, have led to increased interest in home training.

Over the past five years, the statewide home patient population has increased almost 25%, growing at a higher rate than the overall ESRD patient population - a five year average annual change rate (5YAACR) of 5.48% for home patients in North Carolina versus 1.61% for all North Carolina ESRD patient modalities.

	NC ALL Modalities	% Change	NC ICHD Pt Census	% Change	NC Home Pt Census	% Change
12/31/2017	18303		16032		2271	
12/31/2018	19021	3.92%	16601	3.55%	2420	6.56%
12/31/2019	19622	3.16%	17012	2.48%	2610	7.85%
12/31/2020	19547	-0.38%	16838	-1.02%	2709	3.79%
12/31/2021	19495	-1.92%	16685	-0.91%	2810	3.73%
5YAACR		1.61%		1.02%		5.48%

This growth is a result of a variety of factors. Patient choice has always been at the center of everything DaVita does, and greater consideration for home dialysis is now being met with greater physician engagement, intuitive education detailing the benefits of each modality and innovative support programs to enable more patients to choose home treatments when appropriate.

[2] Based on comparative growth rates for twelve-month period ended June 2020.

Our physician partners are referring more patients to home dialysis when appropriate and both new and current dialysis patients are choosing home modalities because of the benefits. Home dialysis patients can dialyze from the comfort of home, giving them better control of their treatment schedules, more time for themselves, their families, their jobs and the activities they enjoyed before starting dialysis. Patients and physicians have further recognized these benefits as they have faced the challenges presented by the COVID-19 pandemic over the past couple of years.

DaVita has developed technologies like home remote monitoring, which helps a patient's care team better manage their care, and a telehealth platform which allows patients to schedule and participate in virtual appointments with their care team, improve clinical outcomes and save on travel time and expense.

All of these elements, which are aligned with the 2019 Executive Order on Advancing American Kidney Health encouraging greater rates of home dialysis to improve the quality of life and care for dialysis patients, are strong evidence that home dialysis will continue to grow in the future and that greater capacity for home training and support is needed.

REASONS FOR THE REQUESTED CHANGES

With regard to ESRD dialysis facilities in the SMFP, "the inventory" in the SMFP has traditionally been understood as in-center dialysis stations. Over the past few years, changes to policies and methodologies in the SMFP and updates to Agency Rules have led to the creation of several categories of dialysis stations that do not fall into this classification of in-center dialysis stations.

When Certificate of Need Regulation - 10A NCAC 14C .2203 Performance Standards was readopted effective January 1, 2021, it included changes related to the development and expansion of home training facilities that had initially been addressed via Declaratory Ruling and a temporary rule change in 2018 and 2019. Specifically, it created a pathway for providers to relocate existing dialysis stations to develop a new dialysis facility to exclusively serve home hemodialysis and home peritoneal patients. The SMFP began tracking dialysis stations at home training facilities in Table 9E: Inventory of Dialysis Home Training Facilities starting with the 2021 SMFP. The Assumptions of the Methodology in Chapter 9 of the SMFP were updated in the 2022 SMFP to exclude these stations from both the county and facility need determination calculations.

Additionally, until 2020, at least 13 outpatient dialysis stations that existed in hospitals were accounted for in Table 9A: Inventory of Dialysis Stations and Calculation of Utilization Rates. When Policy ESRD-3 came into effect in the 2021 SMFP, these stations were removed from the SMFP inventory. Since then, at least two more hospitals have applied to develop at least eight (8) outpatient dialysis stations pursuant to Policy ESRD-3, but these stations are not tracked in Chapter 9 of either the 2022 or 2023 SMFP.

The proposed changes (1, 2, 3, 5.b and 6 above) seek to create clarity about these different categories of dialysis stations (dialysis stations at home training facilities and outpatient dialysis stations on hospital campuses) and ensure that, although these stations are excluded from the **need planning inventory,** they continue to be tracked in a way that gives all those involved in the planning process a clear view of the changes across the inventory of stations in these categories.

The proposed changes at 4 and 5.a seek to address an issue that came to light in 2022. Last year, the Agency received two (2) applications proposing to **develop new dialysis stations at home training facilities**, dedicated exclusively to HHD training. Both applications were denied and in the Required State Agency Findings (RSAF) for both applications, the analyst noted:

> "[T]he applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the proposal would result in an additional dialysis station for which there is no county need determination. Thus, the addition of a dialysis station in Wilson County would increase an existing surplus of dialysis stations in Wilson County. ***An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council***."[3] (Emphasis added).

The proposed changes in this Petition create a pathway for the development of new dialysis stations at home training facilities - stations created outside of the need planning inventory and that would be excluded from the need planning inventory.

The proposed change at 5.a is modeled after a solution the SHCC developed to address a similar gap related to the development of Dedicated C-Section Operating Rooms (OR)[4]. Like Dedicated C-Section ORs, HHD stations at home training facilities are used for a singular purpose. Facilities that provide in-center dialysis services may have been approved to use at least one dialysis station for dedicated training of home dialysis patients. If so, these stations are included in the planning inventory. By definition, however, ***home training facilities*** cannot serve in-center patients and so dialysis stations in a home training facility are dedicated exclusively to home hemodialysis patients for their training and support.

ADVERSE IMPACTS IF THE ADJUSTMENT IS NOT MADE

If the change proposed at 5.a is not made, patient access may be negatively impacted. With respect to the providers, CON applications for new dialysis stations that would be used exclusively for home hemodialysis training, like the two (2) applications received by the CON Section last year, likely would be denied in any service area where the SMFP reflects a surplus of in-center stations thereby preventing a provider from developing services that are more convenient to patients who choose to dialyze at home. Similarly, patients who currently dialyze at an in-center facility, but desire to dialyze at home will be adversely impacted since there may not be a home training facility in their health service are, or in adjacent health service areas, due to a surplus of in-center stations or there are insufficient home training stations at such facility to train them so they can dialyze at home.

ALTERNATIVES CONSIDERED

DaVita considered the following alternative:

> ***Do Nothing***. This is not a suitable alternative because leaving the issues raised in this petition unaddressed only serves to leave the SMFP incomplete and ambiguous. As previously discussed, two (2) applications proposing to develop new dialysis stations at home training facilities were denied by the CON section last year. The Findings for each application pointed not only to the gap in the SFMP presented by the provider's request (no existing method or policy for developing new dialysis stations at a home training facility that would not require a need determination in the SMFP) but also to the only option for remedying that gap in the plan: the development of an alternative policy or method by the SHCC.

[3] RSAF: Wilson Home Dialysis, Project ID# L-12269-22, page 13 & RSAF: Chowan Home Dialysis Project ID #R-12268-22, page 15
[4] See NOTE on page 52 of the 2023 SMFP, Chapter 6 - Operating Rooms

PROPOSED CHANGES WILL NOT RESULT IN UNNECESSARY DUPLICATION

Approval of the petition would not result in unnecessary duplication of services because the stations used at home training facilities are not duplicative of the in-center stations included in the need planning inventory. Additionally, applicants proposing to develop stations pursuant to these changes would still be required to demonstrate that their proposal is consistent with all applicable statutory review criteria, which includes demonstrating the need the patients to be served would have for the proposed services and meeting the performance standards specifically for HHD stations at a home training facility.

CONSISTENCY WITH SMFP BASIC PRINCIPLES

SAFETY AND QUALITY

The requested changes are 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 the changes requested by this Petition, for providers to develop new stations for a growing modality would not negatively impact safety, clinical outcomes, or satisfaction as evidenced by DaVita's experience with its remote monitoring and telehealth platform. Patient satisfaction would most likely be improved by having more options and greater access to multiple modalities.

ACCESS

There is significant evidence that home dialysis will continue to grow in the future and that greater capacity for home training and support is needed. The proposed changes will expand access to patients who would like to choose HHD, especially those in rural and underserved areas where in-center stations are not available to be relocated to develop stations at a home a training facility. The requested changes ensure equitable and timely access for patients by allowing providers to continue to innovate the way they make these services available and address the needs of the growing statewide home patient population.

VALUE

Providing another pathway for the development and expansion of home training facilities will "[encourage] innovation in health care delivery,"[5] which is consistent with the basic principle of value. It will further allow more opportunity for providers to offer training and support services for both home modalities (HHD and PD) under one roof which increase operational efficiency.

CONCLUSION

The proposed changes seek to expand on the work that the SHCC has already done to address the effects of changes to ESRD policies and methodologies in recent years. Adopting the changes proposed in this Petition would help to ensure clarity and transparency in the ESRD definitions and data, as well as help to create greater capacity for home training and support services in the state.

[5] 2023 SMFP, page 3.