Acute Care Services Committee
Agency Report
Petition to Amend the Narrative of the
End-Stage Renal Disease Dialysis Facilities Chapter
Proposed 2024 State Medical Facilities Plan

Petitioner:
DaVita, Inc.

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Request:
DaVita requests multiple changes to the narrative of Chapter 9 End-Stage Renal Disease Dialysis (ESRD) of the *North Carolina 2024 State Medical Facilities Plan (SMFP).*

Background Information:
Chapter Two of the *2023 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 to the State Health Coordinating Council (SHCC) in the spring.

There are two methodologies in the *SMFP* for ESRD services. The facility need methodology projects need for a specific facility, and the county need methodology projects need for the county. When a facility need determination exists, only the facility that generated the need may apply for a certificate of need (CON) to add stations. When a county need determination exists, any current provider may apply for a CON to add stations in an existing facility, and anyone may apply to develop a new facility.

The Centers for Medicare and Medicaid Services (CMS) defines a dialysis station as "an individual patient treatment area that provides sufficient space to accommodate the dialysis equipment and

supplies needed for routine care and any emergency care indicated."[1] CMS does not include regulations to certify stations specifically for home hemodialysis training.

End-Stage Renal Disease providers report data annually for each certified dialysis facility on the current number of certified dialysis stations and the number of patients served by county and modality. Patient utilization is broken down into three modalities: in-center, peritoneal (PD) and hemodialysis (HHD). Two of the three modalities are used in the provision of home dialysis: PD and HHD. Peritoneal dialysis does not require use of a dialysis station while HHD requires the use of a dialysis station. Approved programs provide training to HHD patients and their care partners, along with ongoing support and monitoring. Home hemodialysis patients are trained to perform hemodialysis for six weeks. After the initial training, patients routinely dialyze at home, unlike in-center hemodialysis patients who dialyze three to four times a week at an in-center treatment facility.

Chapter 9 of the *SMFP* defines a home training facility as an ESRD 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 by G.S. § 131E-176(14e). A home training facility must be physically separate from a dialysis facility that provides in-center dialysis services. Dialysis providers must receive approval from the Healthcare Planning and Certificate of Need and Acute and Home Care Licensure and Certification Sections to provide home training and support services at a dialysis treatment facility. A "home training facility" is not required for dialysis providers to train dialysis patients to dialyze at home.

There is not a need determination methodology in the *SMFP* specifically for dialysis stations located within and designated for a "home training facility." The Petitioner is seeking modification to the existing methodology assumptions in Chapter 9 that would allow for the development of new dialysis stations at a "home training facility" without a county need determination or the relocation of existing dialysis stations from an in-center facility.

Analysis/Implications:
The Petitioner requests changes to Chapter 9 "…to 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 Petitioner would like the proposed changes to explicitly indicate a need determination is not required to expand home training facilities.

The methodologies in the *SMFP* only determine need for additional dialysis stations by county and by existing facilities – not by location of stations. This is because a dialysis station is not defined by type of facility (i.e., in-center or training) where it is located. The ability to expand dialysis stations at home training facilities statewide without a county need determination may unnecessarily duplicate existing services and increase dialysis station surpluses in some service areas.

[1]Department of Health & Human Service (DHHS) Center for Medicare & Medicaid Services (CMS). (2018, October 17). *CMS Manual System, Pub. 100-07 State Operations Provider Certification, Transmittal 184.* Retrieved from CMS.Gov: https://www.cms.gov/Regulations-and-guidance/Guidance/Transmittals/2018Downloads/R184SOMA.pdf

As of December 2022, sixty-four *in-center* facilities located in 46 counties reported providing training and support services to HHD patients. Based on Table 9B, ESRD Dialysis Station Need Determinations by Planning Area in the *2023 SMFP*, 71 counties have a combined surplus of 1,073 dialysis stations.

The Petitioner states the home dialysis patient population increased almost 25% between 2017 and 2021 and asserts this growth rate is higher than that of the total dialysis patient population. However, the HHD patient population accounts for no more than 23% of the total home dialysis patient population as shown in Table 1 below.

Table 1. Home Dialysis Population

		Home Dialysis			
SMFP Year	**Data Reporting Year**	**Total Number of Patients**	**Number of PD Patients**	**Number of HHD Patients**	**Percent HHD Patients**
2020	2018	2,380	1,899	481	20.21
2021	2019	2,563	2,001	562	21.93
2022	2020	2,709	2,104	605	22.33
2023	2021	2,810	2,156	654	23.27
2024	2022	2,813	2,177	636	22.61

Data Sources: *Patient Origin Reports associated with 2020-2023 SMFPs,* and *Patient Origin Report for Proposed 2024 SMFP.*

Data in Table 2 shows the total number of HHD patients by reporting year for the most recent five years. In 2022, sixty-nine HHD patients were trained at a home training facility. The performance standards in 10A NCAC 14C .2203, require a CON applicant to document the need for the total number of dialysis stations in a home training facility based on training six HHD patients per station per year. Based on this standard, there is capacity for additional HHD patients. Furthermore, there are four additional home training facilities that have CON issued/not certified, a CON decision rendered (conditional approval), or a CON decision pending to add a combined total of fifteen dialysis stations to provide or expand HHD training. The Petition did not contain evidence that the current home hemodialysis training service capacity is insufficient to meet this level of patient demand.

Table 2. HHD Patients at Home Training Facilities

Data Reporting Year			HHD Patients				
County	**Provider Number**	**Home Training Facility**	**2018**	**2019**	**2020**	**2021**	**2022**
Catawba	34-2699	FMC Hickory Home Program	0	10	7	10	13
Edgecombe	34-2721	Edgecombe Home Dialysis	0	0	1	2	6
Mecklenburg	34-2654	INS Freedom Dialysis	0	8	11	13	23
Mecklenburg	34-2655	INS Charlotte	0	23	31	32	27
Totals			0	41	50	57	69

Data Source: *2018 – 2022 ESRD Data Collection*

The Petitioner asserts that if the proposed change to allow individuals to apply for a CON without regard to the station need determination is not made, "…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 service are[a], or in adjacent health service areas, due to a surplus of in-center stations or there are insufficient home training stations at such a facility to train them so they can dialyze at home." However, the summer petition process presents the opportunity for providers to request an adjustment to a county need determination.

The Petitioner also requested the addition of a definition of the *planning inventory* to Chapter 9. Rather than addressing this request in this report, the Agency will add the definition as a technical change in the *Proposed 2024 SMFP.*

Agency Recommendation:

The Agency supports the standard methodologies for ESRD facilities. Given available information and comments submitted by the March 15, 2023, deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition.