Acute Care Services Committee
Agency Report for
Petition to Change the Need Determination Methodology for End-Stage Renal Disease Dialysis Facilities
Proposed 2024 State Medical Facilities Plan

Petitioner:
Fresenius Medical Care

Contact:
Fatimah Wilson
Director, Certificate of Need
3943 New Bern Avenue
Raleigh, NC 27610
984-268-8421
fatimah.wilson@freseniusmedicalcare.com

Request:
Fresenius Medical Care (FMC) requests to change the need methodology for End-Stage Renal Disease (ESRD) in 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 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] The Centers for Medicare and

[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

Medicaid Services does not include regulations to certify stations specifically for home hemodialysis training.

Annually, ESRD providers report data 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 will routinely dialyze at home, unlike in-center hemodialysis patients who routinely 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 of 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:
According to the Petitioner, Chapter 9's assumptions need to be amended so that there is clarity on the development of new dialysis stations at home training facilities since they are currently not specifically addressed in the *SMFP*. The Petitioner would like the amendments to explicitly indicate a need determination is not required to expand home training facilities.

The Petitioner asserts, "…county and facility need determinations are based on the number of in-center patients divided by the number of certified stations" and that "[h]ome patients and home training stations are not included in the county and facility need determination calculations at all." Because of this the Petitioner states, "…the patient population reflected in a county need determination is, by definition, in-center, patients only. A need determination does not reflect the need or lack of need for stations in home training facilities."

The Petitioner's assertions do not provide a complete description of the two distinct and complex methodologies. For instance, the county need determination methodology is based on county patient data. A county's total patient population is essential to calculating the AARC used to project future patient populations and station need. The methodology uses the total patient

population (including in-center, HHD and PD patients) by county, from five reporting years to calculate the Average Annual Change Rate (AACR). The AACR is used to project total patient population and the total home (i.e., HHD and PD) patient population one year beyond the current reporting year. The projected total home patient population is then subtracted from the projected total home patient population. The remainder is the projected in-center population. The methodology calculations continue to arrive at the county station need determination. Thus, while home patients are deducted from later calculations, they are included in the initial ratios for average rates of use that project total number of patients.

The Petitioner correctly states, "There is no need methodology or need determination in the *SMFP* for dialysis stations in home training facilities." This is because a dialysis station is not defined by the physical location of the station. The methodologies in the *SMFP* only determine need for additional dialysis stations by county and by existing facilities – not by location of stations.

As listed below, there are three methods for adding or expanding dialysis stations.

1. A county need determination allows for the addition of dialysis stations to an existing facility or the development of a new dialysis facility.

2. Policy ESRD-2 allows for the relocation of existing dialysis stations in the same county or a contiguous county.

3. The summer petition process presents the opportunity to adjust a county need determination.

The performance standards in 10A NCAC 14C .2203 allow an existing dialysis provider to submit a CON application that proposes to establish a new dialysis facility dedicated to home hemodialysis or peritoneal dialysis training without a county need determination methodology. The performance standards also only require an applicant to document the need for the total number of home hemodialysis stations in the facility based on training six home hemodialysis patients per station per year as opposed to 3.2 patients per station per week for dialysis stations to be located at an in-center dialysis facility.

While dialysis providers may choose to offer home dialysis training and support services at a dialysis treatment facility, a home training facility is not required for dialysis providers to train patients to dialyze at home. As of December 2022, sixty-four *in-center* facilities located in 46 counties reported providing training and support services to HHD patients.

Table 1 below provides an overview of the number of dialysis patients by treatment modality between 2018 and 2022. As of December 31, 2022, of the 19,012 total dialysis patients 2,813 patients were receiving home dialysis. Most home dialysis patients do not require a station because they receive PD. Patients receiving HHD make up only 3.4% of the total dialysis patient population in the state.

Table 1: Dialysis Patient Origin Data – Five Year Summary

SMFP Year	Data Reporting Year	Number of In-Center Patients	Number of Home Peritoneal Patients (PD)	Number of Home Hemodialysis Patients (HHD)	Total Number of Dialysis Patients	What Percent of Total Dialysis Patients are Home Hemodialysis Patients?
2020	2018	16,352	1,899	481	8,732	2.57
2021	2019	16,725	2,001	562	9,288	2.91
2022	2020	16,838	2,104	605	19,547	3.10
2023	2021	16,492	2,156	654	19,302	3.39
2024	2022	16,199	2,177	636	19,012	3.35

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

The Petitioner provided patient origin data during reporting years 2019 through 2021 to demonstrate a steadily increasing home dialysis population in North Carolina. According to this data, the home patient population increased at an annual average rate of 16.4%. However, the Petitioner does not delineate the type of dialysis treatment facility (i.e., in-center versus home training) where the HHD patients were trained.

Data in Table 2 below 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 petition did not demonstrate 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*

Finally, the Petitioner states that "…home patients and stations in training facilities are not currently part of the inventory or planning process, the current inventory and any resulting surpluses do not reflect the current capacity to meet home dialysis patients' needs" and "…need methodology has no bearing on whether new stations in home training facilities unnecessarily duplicate existing facilities or services." However, an increase in dialysis stations at a home training facility actually increases the county's total number of dialysis stations without considering if the county already has a surplus of dialysis stations and if the dialysis facilities in

the county are currently providing home training and support services to the HHD patients. Therefore, removing the need determination requirement for dialysis stations that providers choose to utilize as home training stations will lead to duplication of dialysis services.

Agency Recommendation:

The Agency supports the standard methodologies for ESRD facilities. Given the 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.