



July 24, 2019

Petition

Petition to Replace the ESRD Facility Need Methodology with a Policy Approach

Petitioner: Fresenius Medical Care and its related dialysis facilities in North Carolina  
Bio-Medical Applications of North Carolina, Inc.  
Bio-Medical Applications of Fayetteville, Inc.  
Bio-Medical Applications of Clinton, Inc.  
RAI Care Centers of North Carolina II, LLC  
Renal Care Group of the South, Inc.  
FMC Morrisville, LLC  
FMC Rock Quarry, LLC  
FMC White Oak, LLC  
FMS ENA Home Dialysis, LLC  
Independent Nephrology Services, Inc.  
Carolina Dialysis, LLC

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**Statement of the proposed change:**

Fresenius Medical Care and its related dialysis facilities in North Carolina respectfully petitions the State Health Coordinating Council (SHCC) to adopt a Policy Approach for new dialysis stations, in lieu of the currently drafted Facility Need Methodology.

The drafted Facility Need Methodology should be removed from the plan.

Draft policy language: Any facility operating at or above 85% utilization may apply for additional dialysis stations, up to a maximum of 10 stations. The applicant must demonstrate the need for the stations and satisfy the performance standards at 10A NCAC 14C .2203(b).

Certificate of Need applications filed pursuant to this policy may be filed twice per year, for the reviews commencing on April 1 and October 1.

**Background:**

Over the course of the past 15 months we—providers, DHSR Staff, and the SHCC—have worked to find a way forward which would radically change the planning and need methodology for ESRD facilities. When this began, the idea was to eliminate the Semi-Annual Dialysis Report and merge the dialysis planning and need determinations into the State

Medical Facilities Plan. In short, we were moving from a twice per year planning and reporting cycle, to a once per year cycle.

The Methodology as currently drafted is not sufficient to ensure adequate access to care for the ESRD patient population across the State of North Carolina. If anything, it will produce unnecessary duplication of services in areas which are already well served, while unfortunately leaving voids in some areas of need.

A policy approach is not a new idea. There are other health services, diagnostic centers for example, which don't have a methodology, but are regulated by policy.

**Reasons for the proposed adjustment:**

The currently drafted methodology produces 874 new dialysis stations, representing an increase of greater than 15% above the current number of dialysis stations. Yet, the ESRD patient population is increasing at a rate of less than 4% annually. Additionally, more patients are choosing home dialysis, meaning fewer dialysis stations will be needed.

A measurement of the annual change of the total ESRD patient population in our state, and the total home patient population, in the same manner as the county five year average annual change rate is calculated, demonstrates that home patient growth is already 50% higher than the total growth.

- The overall ESRD patient population is increasing at 3.92% for the five years ended December 31, 2018.
- In the same five year period, the home patient growth was 5.92%.
- And in 2018, the last measured year, the home growth was 6.5% as oppose to overall growth of 3.8%. Obviously more patients than ever before are dialyzing at home.

In short, the currently drafted methodology appears to create unnecessary duplication of existing health care resources.

**Alternatives considered:**

Fresenius has recommended an increase to the minimum utilization threshold, raising the threshold from 75% to 85% utilization in order for a facility to qualify to apply for additional stations. This change would reduce the number of station need determinations from 874 to 536 stations. This represents an increase of 9.5% over the current number of dialysis stations.

**Adverse effects if the petition is not approved:**

Failure to adopt a policy approach, and to continue with the currently drafted methodology will result in unnecessary duplication of dialysis stations. The dialysis patient population is increasing at a rate of approximately 4.0%. It is reasonable to expect that in order to maintain

the status quo, the dialysis station inventory would similarly increase at approximately 4.0%. The methodology as drafted produces an approximately 15% increase in dialysis stations.

**Unnecessary duplication:**

The very premise of this proposal is to reduce unnecessary duplication of dialysis stations. The currently drafted methodology produces large need determinations. For example:

<u>County</u>	<u>Generated Need</u>	<u>Currently Available</u>	<u>% Change</u>
Cumberland County	47	204	23.04%
Durham	59	215	27.44%
Forsyth	39	199	19.60%
Gaston	36	117	30.77%
Guilford	104	309	33.66%
Mecklenburg	93	544	17.10%
Pitt	21	130	16.15%
Wake	95	404	23.51%

**Conformity with the Basic Principles:**

A policy approach does not have any impact on Safety and Quality, Access, and Value. A policy approach does not preclude development of new dialysis stations within facilities which demonstrate need.

**Safety and Quality:** Change to a policy approach does not affect patient safety or quality of care. A policy approach 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.

**Access:** A policy approach enhances access to care by allowing facilities which have a demonstrated need, to apply for additional stations.

**Value:** A policy approach would allow facilities to develop stations where they are needed, as opposed to development only in facilities which generate need by application of the prescribed methodology. The methodology will be reliant upon older data; for example, the draft 2020 SMFP is publishing data for year-end 2018. The plan would be utilized for applications throughout 2020. Allowing a facility to apply in 2020 with current data would be much more valuable to all concerned. Stations would be generated as they are needed.

**Summary:**

A policy approach for new dialysis stations at existing dialysis facilities is an appropriate way in which to address growth of the patient population. A service area may have multiple facilities, each with varying growth rates. It is appropriate to allow the facilities to increase service capacity consistent with the patient population served by the facility.