FRESENIUS
KIDNEY CARE

**Certificate of Need**
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March 18, 2019

Ms. Elizabeth Brown, Planner
Dr. Amy Craddock, Assistant Chief
Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: DaVita Petition for a Policy Approach to dialysis station need

Ms. Brown, Dr. Craddock and Ms. Frisone:

The following comments are submitted on behalf of Fresenius Medical Care and its related dialysis facilities in North Carolina.

We strongly recommend denial of this petition. Dialysis providers actively engaged with the SHCC and DHSR Staff though out 2019 to arrive at a methodology to replace the Semi-Annual Dialysis Report and move to an annual reporting mechanism included in the State Medical Facilities Plan. The new methodology is too new to change. The current methodology works and serves as an efficient mechanism to identify new station needs across the state. Further the new methodology provides opportunity for "new" and "small" facilities to apply for additional stations as may be determined by the methodology.

We recommend that the SHCC and the Agency give the current plan at least two years before any changes are implemented.

DaVita has provided a Petition and also an oral presentation at the March 4th public hearing. We disagree with the comments from Mr. Santillo of DaVita. Mr. Santillo is only partially correct when he states that a facility with a need determination of zero would have to wait until 2021 to the opportunity to apply for additional stations. A facility with a need determination of zero must wait until the next SMFP to apply for "new" stations. However, that facility could receive stations by way of an application to relocate stations under Policy ESRD-2. The only caveat to such an application is that the facility must demonstrate the need for the additional stations. BMA has already filed such an application (CON Project ID # P-11840-20).

It is not uncommon for stations to be re-distributed, by way of an application based upon an ESRD-2 relocation of stations. Such re-distribution has generally been accepted by the Agency. Providers apply to relocate stations from facilities which do generate need determinations. Many times the provider will file a subsequent application to replace those stations at the facility which transferred stations out.

The DaVita public comments from Mr. Santillo also speak to some facilities demonstrating growth since December 31, 2018. Mr. Santillo characterized the growth as, *"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."*

Growth of this is not uncommon. Frequently, over the many years the SDR was in place, growth of the dialysis facility census meant that the facility could, or would, apply in the next planning cycle for more stations. The DaVita argument seems to be a red herring.

The new methodology adopted by the SHCC has actually resulted in relaxed performance standards, requiring facilities to demonstrate only a 70% utilization (as opposed to the long held standard of 80%). This new standard appears to have increased the number of stations available by way of Facility Need Methodology. Eliminating the Facility Need Methodology and moving to a policy based approach is more likely to increase the number of stations for which providers might apply. A policy approach is more likely to lead to unnecessary duplication of stations.

The SHCC has put the tools in place to allow for appropriate development of dialysis stations. We respectfully disagree with any change to the methodology that relaxes the need determination.

Respectfully,

Jim Swann
Director, Certificate of Need