FRESENIUS KIDNEY CARE

Certificate of Need
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March 21, 2019

Dr. Christopher Ullrich, M.D., Chairman
North Carolina State Health Coordinating Council
c/o NC Division of Health Service Regulation

Amy Craddock, PHD, Assistant Chief
Elizabeth Brown, Planner
Healthcare Planning and Certificate of Need Section
NC Division of Health Service Regulation
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments and Petitions submitted regarding Dialysis Need Methodology

Dear Dr. Ullrich, Dr. Craddock and Ms. Brown:

I'm writing regarding the recent comments and petitions submitted to the SHCC and DHSR / Healthcare Planning and Certificate of Need Office with regard to the Semi-Annual Dialysis Report (SDR) and potential changes to the dialysis need methodologies.

From the outset, Fresenius Medical Care and its related dialysis facilities have embraced the concept of incorporating the dialysis reporting into the State Medical Facilities Plan (SMFP) and a single annual publication, in lieu of the current process which in large measure is the SDR as we know it today. As I noted in our public comments, this process can effectively serve the needs of the dialysis patient population of North Carolina, as long as facilities have the opportunity to apply twice in a 12 month period. Further, Fresenius Medical Care and is related facilities suggest that the current County Need Methodology continue in its current form, with changes appropriate for an annual reporting versus the SDR and it twice annual reporting.

DHSR Healthcare Planning has posted the comments (and petition) offered by DaVita Kidney Care and Wake Forest Baptist Health. The following responsive comments regarding the comments by both are offered.

Comments by DaVita Kidney Care:

1) DaVita has suggested that for the first two SMFPs (2020 SMFP and 2021 SMFP), after transitioning to a single annual report, that *"a County Need Determination should be triggered when the county station deficit reaches a level of 10 or more*

stations, and the SMFP shows that the utilization of each dialysis facility in the county is 85 percent or greater."

We agree, but further suggest the 85 percent utilization should carry forward, and not be limited to just the two years following the change to a single reporting vehicle, the SMFP vs. the SDR.

The SMFP prescribes methodologies for multiple health services beyond the dialysis needs. The prescribed utilization rates vary among the various health services. For example:

- The SMFP Chapter 10, Nursing Care Facilities appear to have a 95% utilization factor (see Step 2 of the need methodology).
- The SMFP Chapter 11, Adult Care Homes appear to have a 95% utilization factor (see Step 2 of the need methodology).
- The SMFP Chapter 15, the Psychiatric Inpatient Services methodology appears to have a 75% utilization factor (see Step 2 of both Bed Need for Children and Adolescents, and Bed Need for Adults).
- The SMFP Chapter 16, Substance Use Disorder appears to require an 85% utilization factor (see Part 1, Step 2 of the Total Bed Need Methodology).

As noted above, three of the prescribed methodologies require an 85% utilization threshold, or higher, before triggering a need determination. While each health service is different, the above services are essentially long term care facilities, where the patient may go for an extended period of time.

Dialysis facilities similarly offer long term care. Except in very rare instances where a patient might regain kidney function, short of a transplant, dialysis patients will require dialysis care for the duration of their lives.

Given the nature of the ongoing requirement for care, and considering that other health services have similar utilization requirements, we believe that an 85% threshold will serve to limit unnecessary duplication and will still allow for identification of need determinations across the State.

2) DaVita has clearly stated that facilities should be able to apply for additional stations twice in a calendar year.

We agree. As noted at the SHCC Public Hearing, and as DaVita highlights, only a few facilities across the State will generate such a need. Thus it is not likely that this is going to severely affect the workload for the CON Agency. However, to limit

a facility to a single application in each year will have adverse impact on those facilities which are heavily utilized, and potentially have adverse impact on the patient population needing dialysis services at those facilities.

3) DaVita has proposed elimination of the Facility Need Methodology in favor of a policy which might prescribe when a facility may apply for additional dialysis stations.

   We don't have significant disagreement on this matter. However, we believe it is more appropriate to retain the Facility Need Methodology. The SHCC, through the SMFP, has prescribed policies in an effort to ensure adequate access to care for the various health services, and also in an effort to prevent the unnecessary duplication of healthcare resources. The absence of a prescribed methodology does not serve to prevent unnecessary duplication. We strongly recommend retention of the Facility Need Methodology, and any necessary changes to the methodology which might arise from a once per year publication of the data.

Comments and Petition by Wake Forest Baptist Health:

1) In paragraph 2A of the petition, Wake Forest Baptist Health (Wake Forest) has proposed elimination of the Facility Need Methodology in favor of a policy which might prescribe when a facility may apply for additional dialysis stations.

   Again, we don't have significant disagreement with this concept, but believe it is more appropriate to retain the Facility Need Methodology. For the same reasons as noted with regard to the DaVita proposal to eliminate the Facility Need Methodology, we believe that this will lead to unnecessary duplication of healthcare resources.

2) Further in paragraph 2A, Wake Forest has also recommended that a facility have opportunity to file a CON application for as many as three times per year.

   We disagree. In large measure the twice per year process has been working exceedingly well. As was noted at the SHCC Public Hearing, the current process has been successful for the past 25 years, since at least 1994. Applying more than twice per year could lead to additional unnecessary duplication.

3) In paragraph 2B, Wake Forest has suggested a revision to Policy ESRD-2 which would limit Policy ESRD-2 CON applications to twice per year (once in the six months January through June, and once in the six months July through December).

   We disagree. The current CON application schedule allows for Policy ESRD-2 application up to four times per year. There is no reason to restrict applications of this nature. First, and most importantly, Policy ESRD-2 applications are not the primary type of applications filed by dialysis providers. The overwhelming majority

of dialysis applications are based upon Facility Need Methodology, which is limited to two opportunities each year. Limiting Policy ESRD-2 applications to twice per year would impede a provider's opportunity for locating stations at facilities close to the patient population which is to be served.

4) Within its Attachment 1, comments on Facility Need Methodology, Wake Forest has suggested that an *"applicant shall demonstrate that all of its existing, approved and propose in-center dialysis stations will be serving 3.2 patients per station as of the end of the first full operating year."*

   We strongly disagree with this. There are multiple counties across the state where a provider may have multiple dialysis facilities. It is overly burdensome to require a provider to demonstrate that each of its facilities in a service area will be serving 3.2 patients per station. This idea contravenes the very nature of Facility Need Methodology.

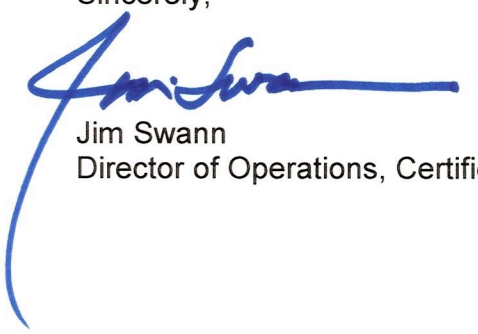
   Facility Need Methodology was developed so that a dialysis facility, with a strong performance, can apply for additional dialysis stations to meet the needs of the patients dialyzing at that facility. It is not uncommon for a provider with multiple facilities in a service area (a county, by definition), to have one or more facilities operating above the 80% utilization threshold, and also have one or more facilities operating below 80% utilization. The idea is to place stations where they are needed.

   Further, CON Agency practice has required providers to demonstrate they are not unnecessarily duplicating existing resources. The Agency has routinely evaluated applications by a provider with multiple facilities within the service area, essentially requiring the provider to demonstrate why it could not relocate existing stations as opposed to develop new stations.

On behalf of Fresenius Medical Care, I look forward to continued dialogue and opportunity to work with the Staff of DHSR Healthcare Planning and Certificate of Need, and the Acute Care Committee of the SHCC. Thank you for the opportunity to share these comments.

If you have any questions please contact me at 910-568-3041, or email jim.swann@fmc-na.com.

Sincerely,



Jim Swann
Director of Operations, Certificate of Need