Public Comments on the Proposed 2021 SMFP from DaVita Kidney Care

DaVita Kidney Care ("DaVita") and its related entities have 110 operational and approved dialysis facilities in North Carolina and provide dialysis care and support to over 6,000 dialysis patients. DaVita would like to address two items regarding the proposed 2021 State Medical Facilities Plan (SMFP). The first item is the proposed Policy ESRD-3. The second is the inventory of home hemodialysis stations.

1. Proposed Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus

Last year, UNC Hospitals submitted a petition for an adjusted County Need determination for 4 outpatient dialysis stations in Orange County. They documented how they were serving a unique subset of patients "in need of outpatient dialysis, but who could not be cared for in an outpatient ESRD facility." However, because UNC Hospital was not able to receive reimbursement for the care of these patients because they had no Medicarecertified outpatient dialysis stations, approval of their petition would provide a path for UNC Hospitals to be reimbursed for treating those patients.

The Agency recommended approval of the adjusted need determination and the SHCC approved the inclusion of the adjusted need in the 2020 SMFP. The review period for applications submitted pursuant to this need began April 1, 2020. However, UNC Hospitals did not submit an application to develop these 4 stations.

At the April Acute Care Services Committee (ACSC) meeting, the Agency proposed adding to the 2021 SMFP Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus, to create a path for hospitals to do what UNC Hospitals requested last year (develop outpatient stations) without going the route of requesting an adjusted need determination.

Although the spirit of the policy is to permit hospitals to apply pursuant to Policy ESRD-3 to serve a relatively small and unique subset of patients, DaVita is concerned about potential unforeseen consequences from the policy in its current form. While the proposed policy indicates the *minimum* number of stations that hospitals must propose to develop, DaVita respectfully requests that the SHCC consider indicating a *maximum* number of stations in the policy as well. Since the performance standard (.2203) will not apply to these stations given that they are for special use and are not anticipated to have high utilization, it makes sense to limit the number of stations that a hospital can apply for under the proposed Policy ESRD-3. Furthermore, the Agency's request that accompanies this proposed policy expressly states that: "It is not the Agency's intent to use the proposed policy to supplant outpatient dialysis facilities in the community." A clearly stated maximum would serve as a "guardrail" that ensures preservation of the Agency's intent in this regard. Should any hospital believe it has a need for stations in excess of the maximum stated in the

SMFP/Policy ESRD-3, that hospital could submit a petition for adjusted County Need determination, as UNC Hospitals did last year.

2. Inventory of Home Hemodialysis Stations

In recent years, providers have applied and been approved to relocate dialysis stations to develop dialysis facilities that exclusively serve home patients. These home standalone programs utilize dialysis stations to train and support home hemodialysis patients. Although patient origin information for these facilities is published by the Healthcare Planning Section, the inventory and utilization for these facilities is not. It is data that was last published in the January 2019 SDR for two facilities in Mecklenburg County (INS Charlotte and INS Huntersville) who were the first home standalone facilities approved to add home hemodialysis stations. It is data that the Planning Section already collects from home standalone facilities via the ESRD Data Collection Forms (see attached December 2019 data submitted for INS Charlotte).

DaVita respectfully asks the SHCC to consider including another table in Chapter 9 that provides details of the inventory and utilization of home hemodialysis stations at facilities that exclusively serve home patients. Because the Plan is a key resource, publishing an inventory and utilization of these home hemodialysis stations will assist providers in planning for providing ESRD services in North Carolina. This is especially true in light of two things, both of which may lead to an increase in the number of these stations:

- The Executive Order on Advancing American Kidney Health issued by the President in 2019; and
- The inclusion of a performance standards for home hemodialysis in the Proposed Readoption of Certificate of Need Regulations – 10A NCAC 14C

Thank you for your consideration of these public written comments from DaVita.

Data Collection Form

End-Stage Renal Disease Facilities December 2019

Section A: Contact Information

1.	Fac	ilitv	Infori	mation
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Facility Name (Do not use all caps) INS Charlotte

Medicare Provider Number (e.g. 34-1533) 34-2655

2. Facility Address

Street Address 6646 Regal Oaks Drive
City Charlotte
State (2 letter abbreviation) NC
Zip Code 28212
Phone Number (use dashes) 704-717-2825

3. County where Facilty is Located

County (Name Only) Mecklenburg

4. Chief Executive Officer or approved designee

Chief Executive Officer
Street Address
City
Huntersville
State (2 letter abbreviation)
Zip Code
Phone Number (use dashes)
Email
Robin.Surane
Robin Surane
9920 Kincey Avenue
Huntersville
NC
28078
704-591-3792
Robin.Surane@fmc-na.cm

5. Facility Administrator

Name Robin Surane

Title Director of Operations

Direct Line Phone Number (use dashes) 704-591-3792

Email Robin.Surane@fmc-na.cm

Data Collection Form

End-Stage Renal Disease Facilities December 2019

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Data Collection Form

End-Stage Renal Disease Facilities
December 2019

Section G: Certification and Signature

This section must be completed and returned along with all other sections of the form to NC DHSR by the established deadline in order for the data submission to be considered complete.

The undersigned Chief Executive Officer or approved designee certifies the accuracy of the information contained on all pages of this form.

Name	Jim Swann
Title	Director, Certificate of Need
Date Signed	1/30/2020

Email jim.swann@fmc-na.com
Phone Number (use dashes) 910-568-3041

Facility Patient Summary

Total Number In-Center Patients	0
Total Number Home Hemo Patients	22
Total Number Home Peritoneal Patients	62
Total Number of Patients	84