Public Hearing Comments on the N.C. Proposed 2021 SMFP Presented on July 29, 2020 by Esther Fleming

Good afternoon. My name is Esther Fleming. I am Director of Healthcare Planning for DaVita Kidney Care. DaVita and its related entities have 110 operational and approved dialysis facilities in North Carolina, providing dialysis care and support to over 6,000 dialysis patients.

This afternoon I'd like to provide comments which 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, UNC Hospital was not able to receive reimbursement for the care of these patients because they had no Medicare-certified 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 and I will note that UNC Hospital did not submit an application this year 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. It creates 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.

We recognize the good intentions behind the proposed policy to address a challenging issue for hospitals, although it's an issue rarely presented to the Agency or the SHCC. In fact, it is my understanding that UNC Hospitals' petition last year was the first of its kind. And, as I noted earlier, UNC Hospital did not ultimately apply to develop the outpatient stations that the SHCC approved.

Although the spirit of the policy is for hospitals to apply pursuant to ESRD-3 to serve a relatively small and unique subset of patients, we are concerned about the unforeseen consequences the policy, in its current form, might bring up in the future. While the proposed policy indicates the minimum number of stations that hospitals should propose to

develop, we ask that the SHCC consider the policy also include a maximum number of stations. In the Agency's request that accompanies this proposed policy, the Agency notes: "It is not the Agency's intent to use the proposed policy to supplant outpatient dialysis facilities in the community." A clearly stated maximum might serve as a "guardrail" that, down the road, would ensure that the Agency's intent did not get lost.

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. We would ask the SHCC to consider including another table in Chapter 9 that provides details of the inventory and utilization of home hemodialysis stations.

Because the Plan is a key resource, including the inventory and utilization of home hemodialysis stations is necessary to help guide providers in our planning for providing ESRD services. This is especially true in light of two things:

- 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 time and I'm happy to answer any questions.