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North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Re: DaVita's Comments Opposing Liberty Healthcare and Rehabilitation Services' Petition to Add Policy ESRD-4 to the 2024 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

DaVita Kidney Care ("DaVita") offers the following comments opposing Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services' ("Liberty") "Petition for Addition of ESRD Policy to the 2024 State Medical Facilities Plan" (Liberty's "Spring 2023 Petition"). As in its Spring petition last year (Liberty's "Spring 2022 Petition"), Liberty's Spring 2023 Petition again proposes that the State Health Coordinating Council ("SHCC") adopt a new policy of statewide effect -- Policy ESRD-4 -- which would allow the development or expansion of kidney disease treatment centers in any nursing home, without regard to the established State Medical Facilities Plan ("SMFP") methodologies for dialysis services, and associated safeguards.

In support of its Spring 2023 Petition, Liberty relies on many of the same arguments it advanced in its Spring 2022 Petition, each of which DaVita addressed in the comments ("DaVita's Spring 2022 Comments") it filed with the Acute Care Services Committee (the "Committee") last Spring. Consequently, DaVita restates herein many of the same criticisms it previously lodged against Liberty's Spring 2023 Petition, which have again gone largely unaddressed. However, DaVita also addresses several new arguments Liberty has raised for the first time in support of proposed Policy ESRD-4, and provides additional reasons why such a policy is ill-advised.

In short summary, the Committee and the SHCC should deny Liberty's Spring 2023 Petition for the following overarching reasons:

1. Liberty's Spring 2023 Petition ignores the clinical realities inherent in providing dialysis services.

2. Proposed Policy ESRD-4 would undermine the state health planning process and unnecessarily duplicate dialysis services statewide.

3. Contrary to Liberty's assertion, no precedent compels the SHCC to adopt proposed Policy ESRD-4.

4. Existing dialysis providers are concerned with patient safety, not avoiding competition.

Because of the adverse consequences that could result from the proposed policy, DaVita urges the Committee and the SHCC to reject Liberty's Spring 2023 Petition and decline to adopt proposed Policy ESRD-4 as part of the 2024 SMFP. **Alternatively**, if the SHCC is inclined to adopt a statewide ESRD petition similar to that which Liberty proposes, DaVita believes the SHCC should include a condition in the policy restricting any nursing home-based dialysis facilities to serving residents of the nursing homes at which such facilities are sited.

Introduction

DaVita and its related entities currently operate over 100 dialysis facilities in North Carolina, providing dialysis care and support to over 6,500 patients, including over 1,000 home dialysis patients. Among those 6,500-plus patients are nursing home patients. Across the country, DaVita facilities support both outpatient and home dialysis patients with the same clinical expectations, clinical protocols, and clinician training, regardless of the site of service. In fact, today, more than 15% of DaVita's patients treat at home.

DaVita's clinical teams uniformly deliver safe and quality care at every step, giving them greater ability to positively impact patient outcomes and reduce health care-acquired infections. DaVita provides equitable access to care and education regardless of modality, including transplant and home dialysis. Its clinical model empowers patients to choose the modality that is right for them, and enables patients to successfully receive their treatment of choice. This standardization of care at scale enables DaVita to systematically identify trends, correct deficiencies, and elevate the care experience for patients who dialyze -- whether in a center or at home -- three times per week, for up to four hours per treatment. In other words, owing to its vast experience and proven business model, DaVita's care is standardized regardless of where services are provided.

The same cannot be said of nursing home providers, who lack the requisite expertise to safely provide dialysis services. The proposed policy would represent a significant change to health planning policy which, if implemented, would adversely affect patients with end-stage renal disease ("ESRD"). The proposed policy would allow nursing home providers who are not properly equipped or trained in dialysis services to provide this complicated -- and life-sustaining -- service.

I. Liberty's Spring 2023 Petition Ignores the Clinical Realities Inherent in Providing Dialysis Services.

As it did last year, in advocating for proposed Policy ESRD-4, Liberty again focuses primarily on resolving the difficulties that nursing home patients encounter in securing dialysis services.[1] But while momentum has recently grown to expand dialysis services into new sites of care, such as nursing homes, the proposed policy's notable failure to appreciate the necessary clinical oversight, support infrastructure and capabilities, educational resources, and continuity of care by patients' nephrologists threatens to negatively impact clinical quality and patient safety. The Spring 2023 Petition should be rejected on the following clinical bases: (A) nursing homes are not equipped to provide dialysis services; and (B) the policy would allow the development of facilities that are not large enough to be economically viable or ensure quality care.

A. Nursing Homes Are Not Equipped To Provide Dialysis Services.

The Safety and Quality Basic Principle, which guides the development of the SMFP, indicates that the Plan should prioritize safety, favorable clinical outcomes, and patient satisfaction, in that order. That Principle reads, in part, as follows:

> "Where practicalities require balancing of these elements, **priority should be given to safety, followed by clinical outcomes**, followed by satisfaction."[2]

Far short of this sentiment, Liberty's 2023 Spring Petition primarily addresses transportation issues, which might be alleviated to some extent by the proposed policy, but only at the expense of patient safety and clinical outcomes.

As it did last year, Liberty discusses safety from the perspective of a **nursing home provider**, but its Petition seeks an avenue to waive the current safety and outcome-focused requirements for new **dialysis services**. In order to safely provide dialysis services, CMS Conditions for Coverage[3] require a multitude of staff, which nursing homes are simply not positioned to employ for the benefit of very small dialysis patient populations. These required personnel include, among others:

- Medical director: a board-certified physician in internal medicine or pediatrics by a professional board who has completed a board-approved training program in nephrology and has at least 12 months of experience providing care to patients receiving dialysis (or, if such physician is not available, another physician approved by CMS);

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[1] Liberty's 2023 Spring Petition, p. 3 ("The intent of the proposed policy is to enable nursing homes to meet the needs of this vulnerable population by eliminating the necessity for uncomfortable patient transports, lengthy patient wait times and treatments at off-site dialysis centers disrupting patient care, meals and comfort.").

[2] 2023 SMFP, p. 2 (emphasis supplied).

[3] 42 C.F.R. § 494.140.

- Nurse manager: a registered nurse who has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in providing nursing care to patients on maintenance dialysis;

- Self-care and home dialysis training nurse: a registered nurse who has at least 12 months experience in providing nursing care and an additional 3 months of experience in the specific modality for which the nurse will provide self-care training; and

- Patient care dialysis technicians: individuals who have completed a training program under the direction of a registered nurse, focused on the operation of kidney dialysis equipment and machines, providing direct patient care, and communication and interpersonal skills, which training program must include the following subjects:

    - Principles of dialysis
    - Care of patients with kidney failure, including interpersonal skills
    - Dialysis procedures and documentation, including initiation, proper cannulation techniques, monitoring, and termination of dialysis
    - Possible complications of dialysis
    - Water treatment and dialysate preparation
    - Infection control
    - Safety

Although Liberty's 2023 Spring Petition -- like its 2022 Petition -- focuses on the advantages of expanding the dialysis service sites of care, it shows little evidence of accounting for the staffing, clinical oversight, educational resources, and continuity of nephrologist care required to operationalize a dialysis facility. Liberty acknowledges the importance of these features, referencing "a memo from CMS regarding home dialysis services in a Long Term Care (LTC) Facility," which requires that home dialysis in a nursing home be "administered and supervised by personnel who meet the criteria for qualifications, training, and competency verification as stated in this guidance **and are provided pursuant to a written agreement between the nursing home and the ESRD facility**."[4] Thus, CMS recognizes that nursing homes are simply not equipped to offer dialysis services without the oversight of an experienced ESRD provider. Despite facing this same criticism during last year's planning cycle, Liberty has not adequately addressed itself to this reality.

Nursing home care and dialysis care are both medically complex. However, the process of providing dialysis -- life-sustaining care -- requires more than the "innovative dialysis technology" that the Liberty Petition references. Liberty has again provided no evidence that it has coordinated or even communicated with any practicing nephrologists to leverage the necessary expertise

[4] Liberty's Spring 2023 Petition, p. 8 (emphasis supplied).

around safely managing the care of dialysis patients in the development of the model of care they are proposing. And there is no evidence that any other North Carolina nursing homes have, either.

B. Proposed Policy ESRD-4 Would Allow The Development of Facilities That Are Not Large Enough To Be Economically Viable Or Ensure Quality Care.

In a report to the Committee, Agency staff has noted that the dialysis facility minimum "threshold of 10 stations is taken from the 'Basic Principles,' which state, "[n]ew facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care. This basic principle was created to assure that new facilities **would have enough patients to assure quality services** and to be financially viable."[5] While the SHCC has previously granted exceptions to the minimum facility size requirement for dialysis facilities in response to petitions (4 stations in Dare County; 5 stations in Macon County; and 5 stations in Graham County), it has done so primarily in response to issues of access in rural and small communities. This is not such a case. Liberty's proposed Policy ESRD-4 would, by definition, have statewide effect. In each of the examples referenced above, the facilities were exempted from facility size requirements on a case-by-case basis, in response to an adjusted need petition addressing idiosyncratic needs.

As discussed in further detail elsewhere in these comments, the special needs petition approach is far preferable to adopting a policy of statewide effect because it allows the SHCC to consider unique circumstances that merit departure from the standard need methodology. If proposed Policy ESRD-4 were adopted, the SHCC would be deprived of the opportunity to consider these special cases. Indeed, if approved, the policy would allow a nursing home provider to apply for a single dialysis station to provide care to one or two patients at a facility. This would frustrate the SHCC's efforts to ensure all dialysis providers in North Carolina operate in a cost-effective manner and provide quality care, as referenced in the Basic Principles.

II. Proposed Policy ESRD-4 Would Undermine the State Health Planning Process and Unnecessarily Duplicate Dialysis Services Statewide.

The Spring 2023 Petition advocates a radical departure from the SMFP methodologies for dialysis services, which will both undermine the state health planning process and result in the unnecessary duplication of services statewide. In addition to the clinical considerations discussed above, this is a standalone reason why the Committee and SHCC should decline to adopt proposed Policy ESRD-4.

A. State Health Planning Process

Liberty asserts that "continuing to submit petitions in the summer for need determinations is problematic, as "[t]he need for outpatient dialysis stations at nursing homes is not based on just

[5] Acute Care Services Committee Agency Report, Adjusted Need Petition for Outpatient Dialysis Stations in Orange County Proposed 2020 State Medical Facilities Plan, September 17, 2019, p. 2 (emphasis supplied).

one specific county or even a few specific counties;" that the "troubling circumstances leading Liberty to submit [its] petition exist statewide nursing homes [sic]."[6] But Liberty fails to provide any evidence whatsoever to substantiate this claim. Tellingly, Liberty omits from its Spring 2023 Petition the following excerpt from its Spring 2022 Petition:

> Currently, twenty-seven (27) of Liberty's nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents.[7]

Likely realizing that its average of 2.96 dialysis patients per facility severely undercuts the need to develop full-scale nursing home-based ESRD facilities, Liberty removed these statistics from its Spring 2023 Petition. And Liberty doesn't substitute any other data -- either from its facilities or other nursing home providers -- to bolster its argument. The Committee and the SHCC should hesitate to adopt a policy with statewide effect on the strength of anecdotes, much less the complete lack of evidence supplied by the Petition.

At a minimum, it is advisable to monitor the results of the adjusted need determination for Mecklenburg County -- included in the 2022 SMFP as a direct result of Liberty's advocacy in last year's health planning cycle -- before considering the policy of statewide effect Liberty proposes. As the Committee will recall, Liberty first advocated for proposed Policy ESRD-4 in its Spring 2022 Petition. The Committee rejected this effort, believing the sounder approach to be Liberty utilizing the summer special needs petition process. Liberty availed itself of this process, seeking an adjusted need for a demonstration project which Liberty, and only Liberty, would be able to develop in Mecklenburg County. The SHCC rejected this petition as well, but nevertheless recommended an adjusted need determination for nursing home-sited ESRD facility stations in Mecklenburg County on its own initiative.

In essence, the Committee (and the SHCC, which adopted the Committee's recommendation), approved a "pilot" adjusted need determination to vet the viability of a nursing home-based dialysis facility (but allowing any interested party to apply for such pilot project). It would be premature to approve a statewide Policy ESRD-4 before knowing who applies for the adjusted need determination in the 2023 SMFP, the progress of that project's development, and the viability of such a project. Nursing home-based dialysis facilities are a brand new concept in North Carolina, and the Committee and SHCC should not rush to codify a policy that would allow such facilities' widespread implementation before assessing their feasibility. Adopting the proposed policy before doing so would undermine the purpose of the state health planning process, and defeat the purpose of the Mecklenburg County adjusted need determination's inclusion in the 2023 SMFP.

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[6] Liberty's Spring 2023 Petition, p. 8.

[7] Liberty's Spring 2022 Petition, p. 8, https://info.ncdhhs.gov/dhsr/mfp/pets/2022/spring/A03-%20PETITION-ESRDPolicyLiberty.pdf.

B. Unnecessary Duplication of Services Statewide

In addition to the foregoing issues, Liberty's proposed Policy ESRD-4 would cause unnecessary duplication of dialysis services across the state, which the CON law and SMFP are specifically designed to avoid.

According to its website, Liberty operates 39 nursing homes in 25 North Carolina counties.[8] Twenty-four of these 25 counties contain existing dialysis facilities. While it omitted any statistics regarding its nursing home patients who require dialysis from its 2023 Spring Petition, Liberty's 2022 Spring Petition stated that "twenty-seven (27) of [its] nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents." It is likely that each of those residents is already treating in one of these existing dialysis facilities. The same can be said of such patients at every other nursing home in the state. Proposed Policy ESRD-4 would duplicate the facilities at which these patients already receive services.

Additionally, if adopted, the proposed policy could have drastic effects on the inventory of dialysis stations in the state. As of February 2023, there are 421 licensed nursing facilities in the State.[9] The proposed policy thus opens the door to the possibility of putting an additional 421 dialysis centers into service, none of which would be required to address Policy GEN-3's "safety and quality" tenets or the safety and quality driven 10-station minimum in the ESRD Chapter Basic Principles and performance standards in the dialysis CON regulatory review criteria.[10]

Policy GEN-3 requires applications to "promote safety and quality in the delivery of dialysis services." A policy such as Proposed Policy ESRD-4, which benefits only certain providers, and purports to address only the patients served by those providers, will only lead to the unnecessary duplication of services. Moreover, it will do so by insulating applicants under the proposed policy from CON review under the quality-focused SMFP policies and rule performance standards. And it will do so in the context of a non-competitive review. Liberty's Petition fails to address these important considerations when proposing Policy ESRD-4.

It is antithetical to the SMFP's Basic Principles to allow providers without the requisite experience to provide a service as medically complex as dialysis without the safeguards afforded by the standard dialysis review criteria discussed above -- from which Liberty seeks to exempt all nursing home providers. Adopting the proposed policy would contravene the CON law and the state health planning process by risking the proliferation of duplicative ESRD facilities of a lower quality across the State.

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[8] *See* https://libertyhealthcareandrehab.com/find-a-facility/ (last accessed Mar. 9, 2023).

[9] *See* https://info.ncdhhs.gov/dhsr/data/Nhlist_co.pdf (last accessed Mar. 9, 2023).

[10] *See* 2023 SMFP, p. 2 (Safety and Quality Basic Principle); p. 114 (ESRD Chapter Basic Principles); p. 408 (10A NCAC 14C.2203 performance standards).

III. Contrary to Liberty's Assertion, No Precedent Compels the SHCC to Adopt Proposed Policy ESRD-4.

As it did last year, in advocating for proposed Policy ESRD-4, Liberty invokes UNC Hospital's 2019 petition for an adjusted need determination in Orange County, which resulted in the SHCC's addition of Policy ESRD-3 to the SMFP.[11] But this time, Liberty asserts that the events leading to the adoption of Policy ESRD-3 constitute precedent requiring the Committee to recommend -- and the SHCC to adopt -- proposed Policy ESRD-4.[12] Not so.

As recounted in Liberty's 2023 Spring Petition, in Summer 2019, UNC Hospitals successfully petitioned for an adjusted need determination for hospital-based outpatient dialysis stations in Orange County, to be included in the 2020 SMFP. But while Liberty correctly notes that "no facility or applicant applied" pursuant to this need determination,[13] it leaves out the obvious: that the COVID-19 pandemic (which started in the United States in early 2020) necessitated hospitals redirecting their resources to cope with the huge influx of COVID patients. As the Committee well knows, CON activity in 2020 was, putting it mildly, anemic.

In the face of the unprecedented obstacles presented by the pandemic, the Committee (and the SHCC) determined it advisable to adopt a statewide policy on their own initiative to address a gap in healthcare delivery for hospital-based dialysis patients. The SHCC's adoption of Policy ESRD-3 in no way requires the Committee or the SHCC to now adopt the policy advocated by Liberty. That is particularly so, where, as here, the intended targets of the proposed policy -- nursing homes -- simply lack the expertise necessary to safely provide dialysis services.

DaVita again urges the Committee to recognize the fundamental differences between hospitals (Policy ESRD-3) and nursing homes (the subject of proposed Policy ESRD-4) in ruling on the propriety of Liberty's Spring 2023 Petition. As stated in DaVita's Summer 2022 Comments, it should be noted that -- unlike nursing homes -- 40% of hospitals in North Carolina already provide inpatient dialysis, which gives hospitals the experience and infrastructure (both physical plant and dialysis-specific ancillary support services and education) that would logically transfer to the provision of outpatient dialysis services in a safe and efficient manner. The same cannot be said for nursing homes.

IV. Existing Dialysis Providers are Concerned with Patient Safety, Not Avoiding Competition.

DaVita is not opposed to working with stakeholders to identify a solution that brings dialysis to where nursing homes residents live. In fact, DaVita has worked toward this goal, having fashioned

[11] Liberty's Spring 2023 Petition, pp. 3-4.

[12] *Id.*, p. 4.

[13] *Id.*

a model focused on bringing care to dialysis patients in nursing homes with the same rigor of dialysis center operations. DaVita's fees for this model -- far from "financially exploitative"[14] -- reflect the care oversight necessary to properly support this patient base and have been commercially reasonable for, and accepted by, over 40 nursing home sites across the country and is growing rapidly. While all health care providers would like to reduce their vendor expenses, achieving that goal cannot come at the expense of safety and quality.

Liberty's Spring 2023 Petition again indicates that Liberty "has had discussions with [dialysis] providers and were, disappointingly, offered terms that are not economically viable . . . ."[15] This begs an important question: if it is not economically viable for nursing homes to contract for an ESRD vendor to oversee the care of nursing home-based dialysis patients, how could it possibly be economically viable for an inexperienced nursing home to employ the required staff for only a few nursing home-based dialysis stations? While Liberty correctly notes that "large dialysis organizations see a need for dialysis in SNF's [sic] based on their own skilled nursing dialysis programs," it fails to recognize that, unlike nursing homes, such organizations have deep experience in providing those services, and can therefore safely offer them in long-term care settings.

Incredibly, in the same breath it accuses existing dialysis providers of seeking to avoid competition in challenging its petition, Liberty argues that the Summer petition process is not a solution because:

> [A] county need determination would allow an established outpatient dialysis provider to potentially apply for and win the Certificate of Need, which would then defeat the purpose of this Petition's goal of providing a more patient-centered dialysis experience in the safest, least disruptive environment.

Contrary to Liberty's argument, it seems it is Liberty -- not established outpatient dialysis providers -- who seeks to avoid competition by avoiding operation of the standard dialysis need methodologies.

DaVita certainly empathizes with nursing home residents who have difficulty accessing dialysis services, and believes that nursing home and dialysis providers should work collaboratively to identify ways to improve access. But the solution to this issue is not to abandon the existing dialysis need methodologies that have served North Carolina so well, for so long. And the solution is certainly not adopting a statewide policy that would allow nursing homes who have no expertise in offering dialysis services to develop ESRD facilities, without having to compete to do so, and without demonstrating even a rudimentary understanding of the clinical challenges involved.

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[14] Liberty's Spring 2023 Petition, p. 8.

[15] *Id.*

DaVita's reasons for opposing Liberty's petition are, and always were, focused on ensuring patient safety in receiving vitally important dialysis services.

V. If the Committee and the SHCC are Inclined to Adopt a Proposal Similar to Proposed Policy ESRD-4, it should Impose a Condition Restricting Service to the Nursing Home Residents that Reside where the Stations are to be Sited.

For the reasons stated above, DaVita believes proposed Policy ESRD-4 should not be adopted. However, if the Committee and SHCC are inclined to include some version of that policy in the 2024 SMFP, they should impose a condition in the policy requiring nursing home applicants seeking to develop such stations to demonstrate that the patients they intend to serve actually reside in the subject nursing homes. Without such a restriction, nursing home applicants could easily end up serving dialysis patients who are not nursing home residents, thereby crowding out the very nursing home residents for whom the stations are intended.

Last year, even while rejecting Liberty's Spring 2022 Petition, the Committee stated that "even though [stations developed pursuant to proposed Policy ESRD-4] would be sited at a nursing home, CMS regulations do not allow providers to limit service to residents of a specific nursing home."[16] While true that **providers** cannot limit such service, **the State** may impose such limitations. Applicable ESRD regulations explicitly mandate that "[t]he facility and its staff must operate and furnish services in compliance with applicable Federal, **State**, and local laws and regulations pertaining to licensure and any other relevant health and safety requirements."[17] Thus, there is nothing to prevent the State -- including the Committee and the SHCC -- from restricting service in order to promote health and safety. In fact, North Carolina's CON Law is predicated on this notion.[18]

Indeed, the State has already imposed such restrictions on other types of ESRD facilities. Specifically, the SMFP's existing Policy ESRD-3 provides that licensed acute care hospitals may apply for a CON to develop outpatient dialysis facilities, provided, *inter alia*, that "**[t]he hospital must document that the patients it proposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are inappropriate for treatment in an outpatient dialysis facility not located on a hospital campus**."[19] Thus, the State already limits

[16] Acute Care Services Committee, Agency Report – Petition to Create an ESRD Policy to Allow for the Development of Expansion of a Kidney Disease Treatment Center at a Skilled Nursing Facility, p. 3, https://info.ncdhhs.gov/dhsr/mfp/pdf/2022/acsc/06%20AgencyReportLibertyFINAL.pdf.

[17] 42 C.F.R. § 494.20.

[18] *See, e.g.*, N.C. Gen. Stat. § 131E-175(7) ("[T]he general welfare and protection of lives, health, and property of the people of this State require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria . . . prior to such services being offered or developed in order that only appropriate and needed institutional health services are made available in the area to be served.").

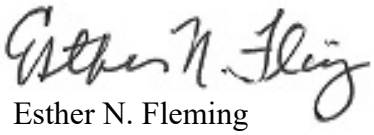
[19] 2023 SMFP, p. 22 (emphasis supplied).

the types of patients that can be served in a hospital-based outpatient dialysis facility. The Committee and the SHCC should do the same to the extent they are inclined to adopt the proposed policy advocated by Liberty.

VI. Conclusion

For the foregoing reasons, DaVita respectfully requests that the Committee and the SHCC reject Liberty's Spring 2023 Petition and refrain from adopting Proposed Policy ESRD-4 in the SMFP. Alternatively, they should impose a condition effectuating the stated intent of the policy; namely, improving access for nursing home dialysis residents.

Sincerely,



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