



TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

March 16, 2022

Dr. Amy Craddock, Assistant Chief, Healthcare Planning
Dr. Sandra B. Greene, Chair, Acute Care Services Committee
Dr. Andrea Emanuel, Planner, Acute Care Services Committee
Ms. Elizabeth Brown, Planner, Acute Care Services Committee
Healthcare Planning Section
Division of Health Service Regulation
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 2023 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

DaVita Kidney Care ("DaVita") offers the following comments opposing the Petition to Add Policy ESRD-4 to the 2023 State Medical Facilities Plan ("SMFP") filed by Liberty Healthcare and Rehabilitation Services ("Liberty"). The Liberty Petition's proposed Policy ESRD-4 would allow the development or expansion of kidney disease treatment centers in any nursing home, without regard to the established SMFP methodologies for dialysis services, and associated safeguards.

Further, Liberty's proposed Policy ESRD-4 fails to properly consider the clinical realities inherent in providing dialysis services, which could easily jeopardize quality of care and patient safety. Because of the adverse consequences that could result from the proposed policy, DaVita urges the Acute Care Services Committee and the State Health Coordinating Council ("SHCC") to reject Liberty's Petition and decline to adopt Proposed Policy ESRD-4 as part of the 2023 SMFP.

Introduction

DaVita and its related entities currently operate 106 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.

In advocating for the proposed policy, Liberty has laudably focused on resolving the difficulties that nursing home patients encounter in securing dialysis services. But while momentum has recently grown to expand dialysis services into new sites of care, such as nursing homes, the proposed policy’s failure to account for 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.

I. Small Number Of Dialysis Patients Per Nursing Home.

A fundamental problem inherent in Liberty’s proposal is this: According to Liberty’s Petition, it currently serves 80 dialysis residents across 27 nursing homes. Thus, any Liberty CON applications arising from this proposed Policy ESRD-4 will likely be for one dialysis station. As discussed below, serious quality concerns arise from such proposed small-scale dialysis operations.

II. Nursing Homes Are Not Well 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:

“Where practicalities require balancing of these elements, **priority should be given to safety, followed by clinical outcomes**, followed by satisfaction.”¹

¹ 2022 SMFP, p. 2 (emphasis supplied).

Far short of this sentiment, Liberty's 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.

Throughout its Petition, 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 Coverage² 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);
- **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;
- **Dietitian**: a registered dietitian with the Commission on Dietetic Registration (RD). A renal dietitian specializes in the nutritional needs of people with chronic kidney disease. Because the kidney diet is highly specialized, renal dietitians have more training in how diet affects kidney function, bones and the heart;
- **Water treatment system technicians**: technicians who perform monitoring and testing of the water treatment system must complete a training program that has been approved by the medical director so that they can ensure that water and equipment used for dialysis meets the water and dialysate quality standards and equipment requirements found in the Association for the Advancement of Medical Instrumentation (AAMI) publication, "Dialysate for hemodialysis"; and

² 42 C.F.R. § 494.140.

- 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 petition focuses on the advantages of expanding the dialysis service sites of care, its Petition shows little evidence of accounting for the staffing, clinical oversight, educational resources, and continuity of nephrologist care required to operationalize a dialysis facility.

Liberty’s petition 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 . . . **under the auspices of a written agreement between the nursing home and the ESRD facility.**” Thus, CMS recognizes that nursing homes are simply not equipped to offer dialysis services without the oversight of an experienced ESRD provider.

III. Proposed Policy ESRD-4 Would Allow The Development of Facilities That Are Not Large Enough To Be Cost Effective Or Ensure Quality Care.

As referenced above, serious quality concerns arise from the proposed small-scale dialysis operations inherent in a CON application filed pursuant to Liberty’s proposed new policy.

In a report to the Acute Care Service 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.”³ 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

³ 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.

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.

That 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.

Liberty's petition indicates that it "has had discussions with [dialysis] providers and were, disappointingly, offered terms that are not economically viable" 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 ESRD-trained staff for only a few nursing home-based dialysis stations? Liberty is almost certainly underestimating the cost of providing dialysis services as it includes not only the personnel listed above, but also providing dialysis-specific supplies, equipment and medications.

To be clear, 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 a model focused on bringing care to dialysis patients at nursing home with the same rigor of dialysis center operations. DaVita's fees for this model—far from "financially exploitative"—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. This number is growing rapidly, including here in North Carolina. DaVita has partnered with a nursing home in Wake County and plans to begin offering home dialysis training and support services to the facility's residents this year. DaVita is currently in discussions with other nursing home providers to provide on-site dialysis care in Durham and Charlotte as well. While all health care providers would like to reduce their vendor expenses, achieving that goal cannot come at the expense of safety and quality.

IV. Proposed Policy ESRD-4 Would Result In The Unnecessary Duplication of Dialysis Services.

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

According to its website, Liberty operates in 25 North Carolina counties. Twenty-four of these 25 counties contain existing dialysis facilities. Liberty's Petition states 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 these residents is already treating in one of these existing

dialysis facilities. Proposed Policy ESRD-4 would duplicate the facilities at which these patients already receive services.

However, this dynamic is not specific to Liberty. If adopted, the proposed policy could have drastic effects on the inventory of dialysis stations, complicating operation of the existing need methodologies. As of February 2, 2022, there are 422 licensed nursing facilities in the State. The proposed policy opens the door to the possibility of putting an additional 422 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. *See* 2022 SMFP, p. 2 (Safety and Quality Basic Principle); p. 116 (ESRD Chapter Basic Principles); p. 414 (10A NCAC 14C.2203 performance standards).

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. 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 exemption.

V. Liberty's Petition Cannot Be Fairly Compared to Hospitals Providing Dialysis Services Under Policy ESRD-3.

Liberty has modeled its request after 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. DaVita respectfully 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 Petition.

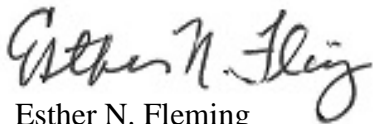
Liberty's Petition suggests that, "[s]imilar to hospitals and their permitted use of outpatient dialysis clinics under Policy ESRD-3, Liberty and other nursing homes throughout the state have the necessary infrastructure to **house** outpatient dialysis stations." But having the space to "house" dialysis stations is a far cry from having the support systems, staffing, and expertise to safely **operate** a dialysis facility. In contrast to 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. It is not enough to assume that having the space to house a dialysis station with the appropriate equipment is enough to warrant waiving the requirement for a new dialysis facility to have at least 10 stations and be subject to the standard criteria. 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. Here, Liberty provides no evidence that it has coordinated or even communicated with any practicing nephrologists to leverage the necessary expertise around safely managing the care of dialysis patients in the development of the model of care they are proposing.

VI. Conclusion

For the foregoing reasons, DaVita respectfully requests that the Acute Care Services Committee and the SHCC reject Liberty’s Petition and refrain from adopting Proposed Policy ESRD-4 in the SMFP.

Sincerely,

A handwritten signature in black ink, appearing to read "Esther N. Fleming". The signature is written in a cursive, flowing style.

Esther N. Fleming
Director, Healthcare Planning