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August 10, 2022

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Dr. Sandra B. Greene, Chair, Acute Care Services Committee
Dr. Andrea Emanuel, Planner, Acute Care Services Committee
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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 for Adjusted Facility Need Determination for Nursing Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

DaVita Kidney Care ("DaVita") offers the following comments opposing Liberty Healthcare and Rehabilitation Services' ("Liberty's") Petition for Adjusted Facility Need Determination for Nursing Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 SMFP ("Liberty's Royal Park Petition"). While Liberty no longer advocates for a policy with statewide effect -- as was the case with its Petition to Add Policy ESRD-4 to the 2023 State Medical Facilities Plan ("ESRD-4 Petition") -- Liberty's Royal Park Petition suffers many of the same infirmities as its ESRD-4 Petition, in addition to a total lack of a "special needs" showing.

For instance, Liberty's Royal Park Petition -- like its ESRD-4 Petition -- would still allow for the development of a kidney disease treatment center in a nursing home without the requisite experience in offering dialysis services, and without regard to the established SMFP methodologies for such services (and the associated safeguards). Moreover, just as its ESRD-4 Petition did, Liberty's Royal Park Petition still fails to properly consider the clinical realities inherent in providing dialysis services, which risks jeopardizing quality of care and patient safety.

Indeed, Liberty does not appear to have materially altered the request underlying its ESRD-4 Petition in any way. Liberty continues to seek an avenue to develop a nursing home-based dialysis center outside the operation of the standard methodology. In other words, **Liberty has simply restyled its ESRD-4 Petition as a special needs petition, but without proving a special need.**

Liberty has failed to address the litany of concerns DaVita and other commenters raised in opposition to the ESRD-4 Petition in the spring petition cycle. Consequently, DaVita restates herein many of the same criticisms it previously lodged against Liberty's proposal in the comments that DaVita filed with the Acute Care Services Committee (the "Committee") of the State Health Coordinating Council ("SHCC") on March 16, 2022 ("DaVita's March Comments"), which are attached as Exhibit 1.

However, Liberty's Royal Park Petition should also be denied for an even more fundamental reason. Special needs petitions -- regardless of modality -- require the identification of service area-specific or facility-specific attributes that warrant departure from the standard need methodology. Pursuant to this special needs petition mechanism, "Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that **special attributes of a service area or institution** give rise to resource requirements that differ from those provided by the standard methodologies and policies."[1] Here, Liberty has made no effort to identify such special attributes, and has therefore failed to state a viable basis for its proposed demonstration project. This omission is fatal to its proposal.

Therefore, DaVita requests that the Committee and the SHCC reject Liberty's Royal Park Petition for the following reasons:

1. Liberty fails to articulate any special attributes that Royal Park of Matthews or Mecklenburg County possess to justify an adjusted, special need determination. See Part I below.

2. For multiple independent reasons, Liberty's Royal Park Petition additionally fails to address the concerns raised by DaVita's March Comments and other commenters in the spring petition process. See Parts II through V below.

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

[1] 2022 SMFP, p. 8 (emphasis supplied).

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. Liberty's Royal Park Petition would allow for the development of a nursing home-based dialysis facility without the oversight of an experienced dialysis provider which, if implemented, would adversely affect patients with end-stage renal disease ("ESRD"). Liberty is simply not properly equipped or trained in dialysis services to provide this complicated—and life-sustaining—service. While momentum has recently grown to expand dialysis services into new sites of care, such as nursing homes, Liberty's Royal Park Petition'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. Liberty's Royal Park Petition Fails To Satisfy The SMFP's Special Needs Petition Requirements.

In submitting Liberty's Royal Park Petition, Liberty avails itself of the special needs petition mechanism for seeking adjusted need determinations outlined in the 2022 SMFP. Pursuant to this mechanism, "Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that **special attributes of a service area or institution** give rise to resource requirements that differ from those provided by the standard methodologies and policies."[2]

However, Liberty's Royal Park Petition fails to show a need for the six (6) dialysis stations proposed for Royal Park of Matthews specifically, or even Mecklenburg County more generally. In fact, Liberty's Royal Park Petition fails to show a need for **any** dialysis stations at Royal Park of Matthews. Therefore, Liberty's proposal fails to show the Committee any special circumstances that merit departure from the SMFP's standard methodology and Basic Principles, which are designed to ensure that dialysis providers in North Carolina operate in a cost-effective manner and provide quality care.

Instead, Liberty adopts wholesale its unsuccessful ESRD-4 Petition rationale that, in Liberty's view, nursing home dialysis patients would be better served by nursing home-based dialysis facilities owned by Liberty. Indeed, in the "Reasons for the Proposed Change" section of the petition, Liberty fails to list any need or demand statistics about Royal Park or Mecklenburg County dialysis patients in any nursing facilities (whether Liberty's or anyone else's). Rather, Liberty again cites, for example, to arguments such as "[n]ationwide staffing shortages" and discusses that such shortages are especially acute in "rural areas." Of course, Charlotte is anything but rural.

[2] 2022 SMFP, p. 8 (emphasis supplied).

Juxtaposing Liberty's Royal Park Petition with other special needs petitions further underscores the shortcomings of Liberty's proposal in this regard:

- In July 2016, one of the Graham County Commissioners requested that an adjusted need determination be included in the 2017 SMFP "for a new dialysis facility in Graham County with a minimum of five [stations] . . . ." This special needs petition was premised on several factors unique to Graham County; namely: (1) that "Graham County is one of very few North Carolina Counties that do not have a dialysis center;" (2) the necessity of some service area residents to "travel 74 miles, roundtrip," to dialysis facilities "through rugged mountainous country" and sometimes "during unpredictable weather patterns;" (3) difficulty of patients traveling for dialysis services during summer months "[d]ue to the seasonal increase in volume at the surrounding dialysis facilities" manifested by tourism; and several other factors. The agency agreed, and recommended approval of the special needs petition. In stark contrast to Liberty's Royal Park Petition, the Graham petitioner clearly articulated service-area specific considerations that warranted departure from the standard methodology.

- In July 2021, PruittHealth, a post-acute care provider, submitted a special needs petition advocating for the addition of an adjusted need determination for 36 skilled nursing facility (NF) beds in Cabarrus County. In support of its petition, PruittHealth cited circumstances uniquely applicable to PruittHealth <u>in Cabarrus County</u>. Specifically, PruittHealth noted that the 2021 SMFP showed a deficit of NF beds in Cabarrus County, which would have allowed the relocation of up to 36 NF beds to Cabarrus County pursuant to Policy NH-6. However, due to the COVID-19 pandemic, the Proposed 2022 SMFP showed a surplus of 160 NF beds in Cabarrus County, which would not allow any further NF beds to be relocated there. According to PruittHealth's special needs petition, "[b]ut for the COVID-19 pandemic and its impact on congregate living facilities in 2020 and 2021, . . . there would have been a need determination for at least 36 additional nursing home beds in Cabarrus County in 2022." As a result, PruittHealth asserted that "COVID-19 artificially suppressed the need for [NF] beds in Cabarrus County for a discrete and limited period," which was not acceptable given "the rapidly growing and aging population." Because it had articulated a county-specific anomaly resulting in no need determination being identified where one likely would have been absent the effects of the pandemic, PruittHealth's petition was approved. In stark contrast, here, Liberty has failed to make such a distinctive showing.

- In July 2020, Atrium Health submitted a special needs petition seeking an adjusted need determination in the 2021 SMFP for a gamma knife in the western part of the State. Citing the growth in its Levine Cancer Institute and the concomitant increase in patients who would benefit from gamma knife procedures, Atrium contended that a special need for additional equipment was merited, especially in view of North Carolina's relatively high population per approved gamma knife when compared to neighboring states. The Agency agreed, and recommended that Atrium's petition be approved. An adjusted need

determination for a gamma knife in HSA III (which includes Mecklenburg County, where Atrium is located) was therefore identified based on facility-specific growth in gamma knife-appropriate patients. Unlike Atrium, Liberty has not cited any such growth (indeed, Liberty has not cited any patient utilization data whatsoever) -- or other special circumstances -- to illustrate a departure from the SMFP's standard methodology is appropriate.

- In July 2021, Vidant Medical Center filed a special needs petition seeking to adjust the operating room need determination in the Pitt/Greene/Hyde/Tyrrell multi-county service area to correct a data error that, if corrected, would result in a need determination for one operating room (as opposed to zero operating rooms, which would be the case if the error were to stand). In recommending approval of Vidant's petition, the agency noted that, "[u]nder normal conditions, the Agency would not consider amending data in such a way that nullifies data from already-approved SMFPs," as "requests for changes to data that impact need determinations must be made during the planning process of the affected SMFP or as soon as the error is noticed." Nevertheless, the agency stated that it "recognizes the extenuating, pandemic-related circumstances that might have prevented complete engagement in the planning process during the summer of 2020," and allowed an adjusted need determination for one operating room. In contrast to Liberty's Royal Park Petition, Vidant clearly identified a service-area specific issue which constituted an extenuating circumstance which merited deviating from the standard planning process.

Because Liberty has not identified any special circumstance specific to Mecklenburg County or Royal Park of Matthews, Liberty has not satisfied the special needs petition requirements. Absent the identification of idiosyncratic needs in Mecklenburg County or at Royal Park of Matthews that merit departure from the standard methodology -- as required of special needs petitions pursuant to Chapter 2 of the 2022 SMFP -- Liberty's Royal Park Petition must be denied.

II. Liberty Will Serve Only A Small Number Of Dialysis Patients.

Another fundamental problem with Liberty's proposal is this: If it is approved to develop the desired demonstration project, Liberty will treat only a very small number of patients. Liberty attempts to minimize this fact. Liberty's Royal Park Petition states that Liberty currently serves 80 dialysis residents across 27 nursing homes. However, Liberty is silent as to how many dialysis patients reside at Royal Park of Matthews, or how it determined that six dialysis stations was the appropriate number of stations to request.

Was the decision to seek permission to develop only six stations driven by its dialysis patient census? By its physical infrastructure? By some other metric? Nobody knows, because Liberty provides no insight into this decision. But one thing is very clear: If Liberty is permitted to develop the demonstration project it requests, it will treat a very small number of patients. As discussed below, serious quality concerns arise from such a small-scale dialysis operation.

III. Liberty Is 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 as follows:

> Where practicalities require balancing of these elements, **priority should be given to safety, followed by clinical outcomes**, followed by satisfaction.[3]

Far short of this sentiment, Liberty's Royal Park Petition primarily addresses transportation issues (like its ESRD-4 Petition did), which might be alleviated to some extent by the Liberty's proposal, but only at the expense of patient safety and clinical outcomes.

Throughout Liberty's Royal Park Petition, Liberty discusses safety from the perspective of a **nursing home provider** while simultaneously seeking 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[4] require a multitude of staff, which nursing home providers like Liberty 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;

- Dietician: a registered dietician with the Commission on Dietetic Registration (RD). A renal dietician specializes in the nutritional needs of people with chronic kidney disease. Because the kidney diet is highly specialized, renal dieticians 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

[3] 2022 SMFP, p. 2 (emphasis supplied).

[4] 42 C.F.R. § 494.140.

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

- 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 Royal Park Petition addresses the advantages of expanding 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's Royal Park Petition implicitly 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**."[5] Thus, CMS recognizes that nursing homes are simply not equipped to offer dialysis services without the oversight of an experienced ESRD provider. Liberty is likewise ill-equipped to offer such services on its own.

In the Agency's Report to the Committee regarding Liberty's ESRD-4 Petition, the Agency noted that it had received comments, like those presented above, expressing doubts and concerns that "nursing homes would be able to provide the services in a safe and medically sound manner."[6] The report further states that the "Agency does not minimize these concerns and caveats, but resolving them is outside the purview of the SHCC."

[5] Liberty's Royal Park Petition, p. 6.

[6] Acute Care Services Committee Agency Report, Petition to Create an ESRD Policy to Allow for the Development or Expansion of a Kidney Disease Treatment Center at a Skilled Nursing Facility, April 12, 2022, p. 4.

We raise these concerns again, not because we expect the SHCC to ultimately resolve these issues, but to highlight that:

1. Liberty's Royal Park Petition fails to address **any** quality of care metrics **for ESRD;** and

2. in evaluating whether to grant a special needs waiver from the need methodology and SMFP policies, it is a central part of the Committee's and SHCC's purview to evaluate whether Liberty's Royal Park Petition:

    a. meets the SMFP's Basic Principles Governing the Development of the Plan, and their priority on safety and clinical outcomes;[7] and

    b. justifies an exemption to the ESRD Chapter's Basic Principles, and their quality of care-driven 10-station minimum (a foundation of the ESRD need methodology).

Here, Liberty's Royal Park Petition presents no evidence to justify deviating from the SMFP's policies and methodology. *See also* Part IV below.

IV. The Demonstration Project Liberty Seeks Is Not Large Enough To Be Economically Viable Or Ensure Quality Care.

As referenced above, serious concerns arise from the proposed small-scale dialysis operations inherent in a demonstration project like Liberty seeks (of course, we cannot even determine how small, since no specific patient need was shown).

A. Economic Viability

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." The staff explicitly notes that "[t]his basic principle was created to assure that new facilities would have enough patients to assure quality services and to be financially viable."[8]

Although 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 proposes to develop this project

[7] *See* 2022 SMFP, p. 2

[8] 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.

in Mecklenburg County, which has: a population of over 1.1 million people;[9] 572 dialysis stations; a surplus of 48 dialysis stations (the second-largest surplus in the State)[10] and a projected surplus of 71 stations.[11] In each of the rural examples referenced above, the facilities were exempted from facility size requirements on a case-by-case basis, in response to a special needs petition addressing idiosyncratic needs. As discussed in Section I above, Liberty's Royal Park Petition does not make such a special needs showing.

As in its ESRD-4 Petition, Liberty's Royal Park Petition indicates that it "has had discussions with [dialysis] providers and were, disappointingly, offered terms that are not economically viable and were, in fact, cost-prohibitive." But Liberty has still not addressed the important question raised in DaVita's March Comments: If it is "not economically viable" and is in fact "cost-prohibitive" 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? Again, Liberty is almost certainly underestimating the cost of providing dialysis services given the necessary personnel listed above, as well as the required dialysis-specific supplies, equipment, and medications (which Liberty has not addressed at all).

DaVita has demonstrated its willingness to work with stakeholders to identify a solution that brings dialysis to where nursing homes residents live. As stated in DaVita's March Comments, DaVita has fashioned a model focused on bringing care to dialysis patients at nursing home with the same rigor of dialysis center operations, with fees reflecting the care oversight necessary to properly support such patients (which are commercially reasonable, having been accepted by over 40 nursing home sites across the country). 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 also currently in discussions with other nursing home providers to provide on-site dialysis care in Durham and Charlotte as well. DaVita believes it is advisable to wait and see how a nursing home model operated under the standard methodology is demonstrated to work before taking the leap of allowing a nursing home to provide dialysis services it is not experienced in or equipped to provide. While all health care providers would like to reduce their vendor expenses, achieving that goal cannot come at the expense of safety and quality.

B. Ensuring Quality Care

Liberty's Royal Park Petition (as in its ESRD-4 Petition) conflates two distinct concepts: Having "the necessary infrastructure to **house** outpatient dialysis stations" and having the support systems, staffing, and expertise to safely **operate** a dialysis facility. In seeking a waiver of the SMFP requirement that a new dialysis facility have at least 10 stations, Liberty mistakenly asserts that this requirement "was based on the presumed size (*i.e.*, number of dialysis stations) needed to make a new ESRD center viable," which it states is "a concern not present in the proposed

[9] *See* https://www.census.gov/quickfacts/mecklenburgcountynorthcarolina (last accessed Aug. 5, 2022).

[10] *See* 2022 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 137.

[11] *See* Proposed 2023 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 132.

demonstration project which would be housed in an existing, viable skilled nursing facility." According to Liberty, because it has the ability to house six stations without the necessity of major construction, the cost-effectiveness of its proposal is not in question. But cost-effectiveness is only one aspect of what the first SMFP Basic Principle **for ESRD facilities** protects, and is less crucial than the other reason underlying the 10-station minimum: "assur[ing] quality of care." Liberty's failure to recognize—or its willingness to overlook—this important feature underscores the need for the Committee and SHCC to deny Liberty's Royal Park Petition.

Equating the possession of physical infrastructure for dialysis stations with having the personnel and expertise to operate them is problematic. 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. Liberty again 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 it is proposing. And it does so while overlooking the primary rationale for requiring a minimum of 10 stations to begin with -- assuring quality care.

V. The Demonstration Project Liberty Seeks Would Result In The Unnecessary Duplication of Dialysis Services.

In addition to the foregoing issues, Liberty's Royal Park Petition would cause unnecessary duplication, which the CON law and SMFP are designed to avoid. *See* N.C. Gen. Stat. §§ 131E-175(3), (4), (6) and 131E-183(a)(6). The site at which Liberty proposes developing the desired demonstration project -- Royal Park of Matthews -- is located in Mecklenburg County. As noted above, Mecklenburg County has the second-highest surplus of dialysis stations in the State, in both the 2022 SMFP and the Proposed 2023 SMFP. By definition, Mecklenburg County does not require any further dialysis stations at this time.

There are 23 existing dialysis facilities in Mecklenburg County.[12] At least seven (7) dialysis facilities (and perhaps nine) are within 10 miles of Royal Park of Matthews,[13] and 21 dialysis facilities are within 20 miles of Royal Park of Matthews.[14] The SMFP's Basic Principles provide that "end-stage renal disease treatment should be available within 30 miles from the patients' homes."[15] There is no question that Royal Park of Matthews residents have readily available access to dialysis services under that SMFP measure.

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[12] *See* Draft 2023 SMFP, Chapter 9: Dialysis Data by County of Patient Origin, December 2021 Data (updated as of 6-6-2022) *https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/01-Ch9PatOrigin_Final.pdf*

[13] *See* Exhibit 2 (Map Showing Dialysis Facilities Within a 10 mile radius of Royal Park of Matthews).

[14] *See* Exhibit 3 (Map Showing Dialysis Facilities Within a 20 mile radius of Royal Park of Matthews).

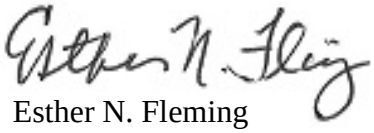
[15] 2022 SMFP, p. 116 (ESRD Chapter Basic Principles).

Liberty's Royal Park Petition states that "twenty-seven (27) of [its] nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents." Despite that geographic dispersion, Liberty proposes to develop its demonstration project in a county with a very large number of existing dialysis facilities, with a huge surplus of stations. Liberty's Royal Park Petition would put an additional six dialysis stations into service where none are needed. These stations would not be required to address the safety- and quality-driven 10-station minimum in the ESRD Chapter Basic Principles and CON performance standards.[16] As in its ESRD-4 Petition, Liberty's Royal Park Petition fails to address these important considerations.

VI. Conclusion

For the foregoing reasons, DaVita respectfully requests that the Committee and the SHCC reject Liberty's Royal Park Petition and refrain from inserting any adjusted need determination for a nursing home-based dialysis demonstration project in the 2023 SMFP for Mecklenburg County or elsewhere.

Sincerely,



Esther N. Fleming
Director, Healthcare Planning

[16] *See id.*, p. 2 (Safety and Quality Basic Principle); p. 116 (ESRD Chapter Basic Principles); p. 414 (10A N.C.A.C. 14C.2203 performance standards).

Exhibits

1. March 16, 2022 Comments That DaVita filed ("DaVita's March Comments") Opposing Liberty's ESRD-4 Petition

2. Map Showing Dialysis Facilities Within a 10 mile radius of Royal Park

3. Map Showing Dialysis Facilities Within a 20 mile radius of Royal Park

Exhibit 1

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
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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 Coverage[2] 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.

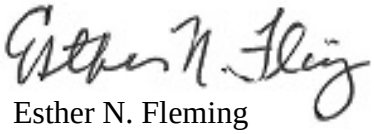
Liberty's Petition suggests that, "[s]imilar to hospitals and their permitted use of outpatient dialysis clinics under Policy ESRD-3, Liberty and other nursing homes throughout the state have the necessary infrastructure to **house** outpatient dialysis stations." But having the space to "house" dialysis 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,



Esther N. Fleming
Director, Healthcare Planning

Exhibit 2

Mecklenburg County ESRD Facilities

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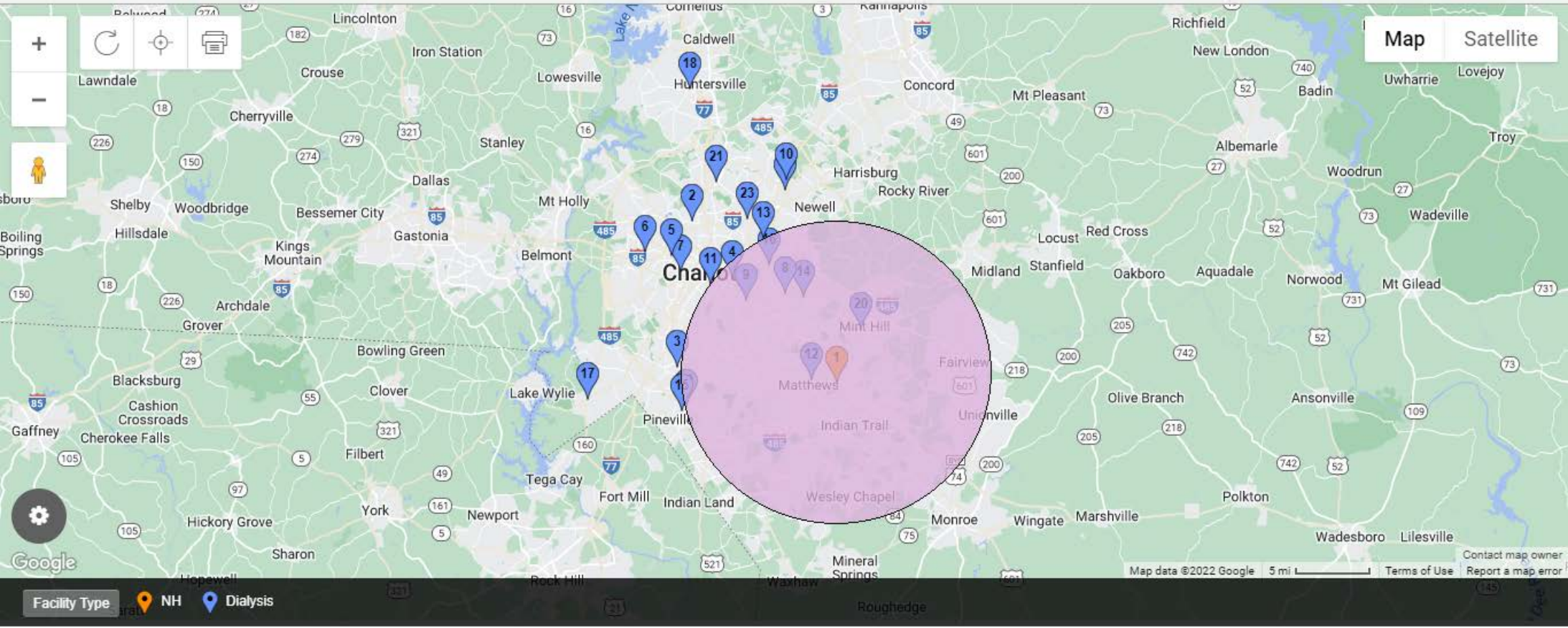

Facility Type NH Dialysis

	County	Facility Identifi-cation Number	Provider Number	Facility	Address	City	State	Zip	Facility Type
1	Mecklenburg			Royal Park of Matthews	2700 Royal Commons Ln	Matthews	NC	28105	NH
2	Mecklenburg	960156	34-2581	BMA Beatties Ford	1534 N Hoskins Road	Charlotte	NC	28216	Dialysis
3	Mecklenburg	970826	34-2594	BMA Nations Ford	7901 England St	Charlotte	NC	28273	Dialysis
4	Mecklenburg	970301	34-2605	BMA of East Charlotte	1334 Central Avenue	Charlotte	NC	28205	Dialysis
5	Mecklenburg	955792	34-2554	BMA West Charlotte	3057 Freedom Drive	Charlotte	NC	28208	Dialysis
6	Mecklenburg	150477	34-2731	Brookshire Dialysis^^	5601 Tuckaseegee Rd	Charlotte	NC	28208	Dialysis
7	Mecklenburg	955930	34-2548	Charlotte Dialysis	2321 W Morehead Street	Charlotte	NC	28208	Dialysis
8	Mecklenburg	001554	34-2627	Charlotte East Dialysis	5627 Albemarle Road	Charlotte	NC	28212	Dialysis
9	Mecklenburg	944671	34-2552	DSI Charlotte Latrobe Dialysis	3515 Latrobe Dr	Charlotte	NC	28211	Dialysis
10	Mecklenburg	955380	34-2591	DSI Glenwater Dialysis	9030 Glenwater Dr	Charlotte	NC	28262	Dialysis
11	Mecklenburg	955947	34-2503	FMC Charlotte	928 Baxter Street	Charlotte	NC	28204	Dialysis
12	Mecklenburg	080137	34-2681	FMC Matthews	910 Park Center Drive	Matthews	NC	28105	Dialysis
13	Mecklenburg	955788	34-2549	FMC of North Charlotte	5220 N Tryon St A	Charlotte	NC	28213	Dialysis
14	Mecklenburg	150024	34-2719	Fresenius Kidney Care Regal Oaks	6646 Regal Oaks Drive	Charlotte	NC	28212	Dialysis
15	Mecklenburg	160337	34-2750	Fresenius Kidney Care Southeast Mecklenburg	10501 Centrum Pkwy	Pineville	NC	28134	Dialysis
16	Mecklenburg	150435	34-2738	Fresenius Medical Care Aldersgate	3211 Bishops Way Ln Suite 2000	Charlotte	NC	28215	Dialysis
17	Mecklenburg	120485	34-2713	Fresenius Medical Care Southwest Charlotte	14166 Steele Creek Rd	Charlotte	NC	28273	Dialysis
18	Mecklenburg	130490	34-2707	Huntersville Dialysis	9622 Kincey Ave	Huntersville	NC	28078	Dialysis
19	Mecklenburg	070499	34-2655	INS Charlotte (to be replaced with INS Victory Home)	8430 University Executive Park Drive Suite 685	Charlotte	NC	28262	Dialysis
20	Mecklenburg	070389	34-2692	Mint Hill Dialysis	11308 Hawthorne Dr	Mint Hill	NC	28227	Dialysis
21	Mecklenburg	060083	34-2663	North Charlotte Dialysis Center	6620 Old Statesville Road	Charlotte	NC	28269	Dialysis
22	Mecklenburg	170127	34-2523	South Charlotte Dialysis	10504 Park Rd	Charlotte	NC	28210	Dialysis
23	Mecklenburg	150478	34-2736	Sugar Creek Dialysis	5100 Reagan Dr Ste 10	Charlotte	NC	28206	Dialysis

Exhibit 3

Mecklenburg County ESRD Facilities

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