PETITION FOR RULEMAKING

To: Mark Payne, Director
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
2701 Mail Service Center
Raleigh, North Carolina 27699-2701

Pursuant to N.C. Gen. Stat. §§ 131E-183(b), 150B-20, 150B-21.1(a)(6), and 10A N.C.A.C. 14A.0101, the undersigned Petitioner, DaVita Inc. ("DaVita"), petitions and requests that the North Carolina Department of Health and Human Services, Division of Health Service Regulation (hereafter, the "Department") adopt a temporary rule establishing a review criterion to complement the adjusted need determination identified in the Proposed 2023 State Medical Facilities Plan ("SMFP") for nursing home facility-based outpatient dialysis stations in Mecklenburg County (the "Adjusted Need Determination").

I. Introduction

DaVita proposes that the Department adopt the following proposed temporary rule (the "Proposed Rule") -- as a temporary rule effective January 1, 2023 -- to ensure that the Adjusted Need Determination conforms to the intent underlying its adoption:

> **Proposed Rule**
>
> Any nursing home applicant applying to develop nursing home-based outpatient dialysis stations pursuant to the 2023 adjusted need determination for Mecklenburg County shall document that the patients it proposes to serve are residents of the applying nursing home.

The Proposed Rule would be added to the Performance Standards for End Stage Renal Disease Services at 10A NCAC 14C.2203 as an additional condition of approval for CON applicants filing in response to the Adjusted Need Determination.

The Proposed Rule is needed in order to impose conditions upon Certificate of Need ("CON") applicants seeking to develop nursing home facility-based outpatient dialysis stations pursuant to the Adjusted Need Determination. Specifically, the Department should require 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 ("general community patients"), thereby crowding out the very nursing home residents for whom the stations are intended. That would be a very unfortunate, unintended consequence of this Adjusted Need Determination. DaVita's proposed rule is necessary to avoid that unintended circumvention.

DaVita and its related entities operate over 100 dialysis facilities in North Carolina, eight of which are located in Mecklenburg County. Those eight Mecklenburg County facilities contain 201 outpatient dialysis stations. DaVita and its related entities will be substantially prejudiced and aggrieved if the Proposed Rule is not adopted. DaVita and its related entities will be directly and negatively impacted by any circumvention practices (and resulting unnecessary duplication) that could occur absent the Proposed Rule.

The Department possesses the authority to adopt such a temporary rule because it is vested with rulemaking authority by N.C. Gen. Stat. § 131E-183(b), and the rule is needed "to establish[] review criteria . . . to complement . . . the State Medical Facilities Plan ["SMFP"] approved by the Governor" and "addresses a matter included in the [SMFP]."[1]

[1] N.C. Gen. Stat. § 150B-21.1(a)(6).

The Proposed Rule is necessary to ensure that CON projects approved pursuant to the Adjusted Need Determination conform to the intent of the Adjusted Need Determination, serving the applicant's on-site nursing home residents. Without this Proposed Rule:

1. the whole purpose of the Adjusted Need Determination could easily be circumvented and undermined; and
2. the Adjusted Need Determination will likely result in unnecessary duplication of general purpose Mecklenburg County dialysis stations, a county with one of the State's largest dialysis station surpluses.[2]

II. Background

The Adjusted Need Determination resulted directly from the efforts of an existing nursing home provider, Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty"), which sought an avenue to develop its own nursing home-based outpatient dialysis facility in Mecklenburg County through the State Health Planning Process. DaVita briefly summarizes those efforts below.

A. Liberty's Spring Petition

In the spring of 2022, Liberty filed its "ESRD-4 Petition."[3] Liberty urged the State Health Coordinating Council ("SHCC") -- through the SHCC's Acute Care Services Committee (the "Committee") -- to adopt proposed Policy ESRD-4, which would allow skilled nursing facilities to apply for dialysis stations outside of the dialysis need methodology statewide.[4]

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[2] *See* 2022 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 137; Proposed 2023 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 132.

[3] Exhibit A.

[4] *Id.*, at pp. 1-2.

Liberty's stated purpose was to dialyze fragile nursing home residents on-site, to avoid transporting them.[5] Thus, Liberty articulated that "[t]he intent of the proposed policy is to enable nursing homes to be reimbursed for providing outpatient or home dialysis **to patients that are better suited to being served in the nursing home**."[6] Liberty added that "**this proposed policy is not intended to displace outpatient dialysis facilities in the community**," and that it "sees a need for the delivery of dialysis services in both environments."[7]

In keeping with that central theme of dialyzing fragile nursing residents on-site, Liberty reasoned that:

> [T]raveling to offsite dialysis can be very disruptive to the health and welfare of this [nursing facility] population, most of whom are already frail and often have multiple health problems. The intent of the proposed policy will 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 center[s] disrupting patient care, meals, and comfort.[8]

The Committee recommended denial of Liberty's ESRD-4 Petition based on the Department's Healthcare Planning Staff (the "Agency"), which professed "support[] [for] the standard methodologies for ESRD facilities."[9] The Committee [and later the SHCC] agreed with the Agency that a proposed policy of statewide effect was inappropriate, given the availability of the summer petition process, pursuant to which petitioners can seek adjusted need determinations

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[5] *Id.*, at p. 5.

[6] *Id.* at p. 6 (emphasis supplied).

[7] *Id.*

[8] *Id.* at p. 5.

[9] *See* https://info.ncdhhs.gov/dhsr/mfp/pdf/2022/acsc/06%20AgencyReportLibertyFINAL.pdf, at p. 4.

that account for "special attributes of a service area or institution" which "give rise to resource requirements that differ from those provided by the standard methodologies and policies."[10]

In passing, the Agency noted that "even though [a hypothetical adjusted need determination would provide that] stations would be sited at a nursing home, CMS regulations do not allow providers to limit service to residents of a specific nursing home."[11] Here, however, the Agency importantly failed to point out that **the State** may impose such limitations. Applicable 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."[12] There is nothing to prevent the State from restricting service in order to promote health and safety. In fact, North Carolina's CON Law is predicated on this notion.[13]

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**." See 2022 SMFP, pp. 22-23. Thus, the State already limits the types of patients that can be served in a hospital-based outpatient

[10] 2022 SMFP, p. 8.

[11] *Id.*

[12] 42 C.F.R. § 494.20.

[13] *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.").

dialysis facility. The Agency should do likewise here with nursing home facility-based outpatient dialysis stations by adopting the Proposed Rule.

Similarly, for many years, the Agency, the SHCC, and the Governor have restricted which types of patients and residents can be served in Medicare-certified nursing homes and licensed adult care homes. See 2022 SMFP, pp. 23-26 (Policies NH-2 and LTC-1 for such facilities within continuing care retirement communities ("CCRCs")). Thus, the Agency can clearly impose a rule -- like the Proposed Rule -- that imposes restrictions on the types of patients a CON applicant may serve.

B. Liberty's Summer Petition

Following the rejection of its ESRD-4 Petition, Liberty then filed with the SHCC -- through the Committee -- a summer petition we will call "Liberty's Royal Park Petition."[14] While Liberty no longer advocated for a policy of statewide effect, it nevertheless sought an avenue to develop an outpatient dialysis facility at its Mecklenburg skilled nursing facility -- Royal Park of Matthews -- by restyling its ESRD-4 Petition as one seeking permission to develop a nursing home-based dialysis facility outside the operation of the SMFP's standard methodology.

Specifically, Liberty requested that the SHCC identify an adjusted need for a nursing home dialysis pilot demonstration project at Royal Park, which would allow Liberty to develop such a facility. The stated rationales for Liberty's Royal Park Petition mirrored those cited in its ESRD-4 Petition, which is to dialyze fragile nursing residents on-site, to avoid transporting them.[15]

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[14] Exhibit B.

[15] *Id.*, at pp. 5-6.

C. Adoption of Agency-Recommended Alternative to Liberty's Royal Park Petition

The Agency recommended denying Liberty's Royal Park Petition as written, and instead recommended an adjusted need determination for six outpatient dialysis facility stations in Mecklenburg County, to be allocated for development within a nursing home facility or "proximate to the nursing home building." The Committee and the SHCC adopted the Agency's recommendation, thereby placing the Adjusted Need Determination in the Proposed 2023 SMFP.[16] Because there was no formal commenting opportunity after the Agency proposed its own need determination -- departing from Liberty's specific Royal Park Petition request -- there was no formal opportunity for DaVita's comments on this new Agency proposal to be heard by the Committee or the SHCC. In the very short window of time after the Agency's recommendation, DaVita sought to urge the SHCC to add a condition similar to the Proposed Rule. There is no evidence that the full SHCC ever reviewed or considered DaVita's request and concerns.

III. Reasons for the Proposed Rule

As demonstrated above, the Adjusted Need Determination is a direct result of, and response to, Liberty's ESRD-4 Petition and Liberty's Royal Park Petition. Liberty's primary rationale for both petitions was that nursing home residents face unique circumstances that merit deviating from the SMFP's standard methodology for ESRD facilities, such that nursing homes should be allowed an opportunity to develop nursing home facility-based outpatient dialysis stations to serve their own patients to avoid transporting fragile nursing home residents.

The SHCC adopted six (6) conditions recommended by the Agency and Committee (the "Adjusted Need Determination Conditions"). Adjusted Need Determination Condition #5

[16] The Agency's recommended Adjusted Need Determination, adopted by the SHCC, is contained at Exhibit C.

excludes these specialized facilities and associated stations from the dialysis station planning inventory and from the county and facility need methodologies.[17]

Unfortunately, the SHCC failed to include one necessary condition, which the Agency may now insert by rule. The Adjusted Need Determination stops short of adequately ensuring the demonstrated intent behind the Adjusted Need Determination -- that such stations be devoted to "patients that are better suited to being served in the nursing home."[18] The Adjusted Need Determination would currently allow a successful nursing home applicant to offer dialysis services to any individual without restriction, including those who do not actually reside at the applying nursing home, thus defeating the Adjusted Need Determination's purpose.

Given the numbers of nursing home resident-dialysis patients that Liberty cited in its petitions (and given the Adjusted Need Determination's limit of six stations), it is highly likely that any given successful nursing home applicant may only prove the need for a single dialysis station (or a small number in any event). Unless the limited available patient time on that dialysis station (or stations) is exclusively devoted to serving that nursing home's residents, the stations applied for under this Adjusted Need Determination may not be available for the very resident-patients for whom they were intended. Instead, the general community patients will crowd out the nursing home residents for whom the stations are intended, and the Adjusted Need Determination will result in unnecessary duplication of general purpose Mecklenburg County dialysis stations, a county with one of the State's largest dialysis station surpluses.[19] As referenced in Part I, DaVita and its related entities operate eight dialysis facilities (including 201 outpatient dialysis stations)

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[17] Exhibit C, p. 3.

[18] Exhibit A, p. 6; Exhibit B, p. 7.

[19] *See* 2022 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 137; Proposed 2023 SMFP, Table 9B: ESRD Dialysis Station Need Determinations by Planning Area, p. 132.

in Mecklenburg County, and would be directly and negatively impacted by any unnecessary duplication that could occur absent the Proposed Rule.

In its original petition, Liberty stated that its proposal "is not intended to displace outpatient dialysis facilities in the community."[20] However, even if petitioner Liberty intends to honor its stated objectives and serve only its on-site residents if it is an approved applicant, anyone can apply for the stations under the Adjusted Need Determination. Thus, the standards should bind any applicant to that same intent behind the Adjusted Need Determination. The six existing SHCC conditions do not enforce that intent. DaVita's Proposed Rule would enforce that intent.

Therefore, it is necessary to conform the Adjusted Need Determination to the reasons underlying its adoption by requiring CON applicants seeking to develop nursing home facility-based outpatient dialysis stations pursuant to the Adjusted Need Determination to document that the patients they propose to serve are residents of the applying nursing home. That would ensure that the original intent of the Adjusted Need Determination is met and would be consistent with the Adjusted Need Determination's Condition #5, which (as previously referenced) excludes these specialized facilities and associated stations from the general purpose dialysis station planning inventory and need methodologies.[21]

[20] Exhibit A, p. 6.

[21] Exhibit C, p. 3.

IV. Text of the Proposed Temporary Rule for Adoption

As stated in Part I, DaVita proposes that the Department adopt the following temporary rule to conform the Adjusted Need Determination to the intent underlying its adoption:

Proposed Rule

> Any nursing home applicant applying to develop nursing home-based outpatient dialysis stations pursuant to the 2023 adjusted need determination for Mecklenburg County shall document that the patients it proposes to serve are residents of the applying nursing home.

The Proposed Rule would be added to the Performance Standards for End Stage Renal Disease Services at 10A NCAC 14C.2203 as an additional condition of approval for CON applicants filing in response to the Adjusted Need Determination.

V. Statement of the Effect on Existing Rules/Orders

On information and belief, the Proposed Rule will have no effect on existing rules and orders. The Adjusted Need Determination to which the Proposed Rule will apply will appear only in the 2023 SMFP. All other laws and rules that apply to CON review in general, and ESRD need determinations in particular, will remain in full force and effect. Furthermore, all extant policies in the SMFP will apply with full force. The proposed rule will do nothing more than require nursing home applicants seeking to develop nursing home facility-based outpatient dialysis stations to do what was intended all along: treat only patients who reside at the applicant nursing home.

VI. Statement of the Effect of the Proposed Rule on Existing Practices in the Area Involved

DaVita is not aware of any nursing home providers in North Carolina that own or operate their own outpatient dialysis facilities, whether in nursing homes or otherwise. Thus, the only

effect the proposed temporary rule will have on existing practices in the area involved is to require Mecklenburg County nursing homes seeking to develop nursing home facility-based outpatient dialysis stations pursuant to the Adjusted Need Determination to do what was intended all along: treat only patients who reside at the applicant nursing home.

VII. Name and Address of Petitioner

DaVita submits this Petition through its undersigned attorneys. The name and address of the Petitioner is as follows:

DaVita, Inc.
c/o Esther N. Fleming
Director, Healthcare Planning
2321 West Morehead Street
Charlotte, NC 28208

This the 21st day of October, 2022.

K&L GATES LLP

By: Gary S. Qualls

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Exhibits

A. Liberty's ESRD-4 Petition

B. Liberty's Royal Park Petition

C. Acute Care Services Committee Agency Report

Exhibit A

EXHIBIT
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A

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PETITION FOR ADDITION OF ESRD POLICY TO THE 2023 STATE MEDICAL FACILITIES PLAN

1. **Name, address, email address, and phone number of the Petitioner:**

Name: Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty")
ATTN: David Holmes, Vice President of Business Development and Timothy Walsh, Senior Financial Analyst
Address: 2334 S 41st Street, Wilmington, NC 28451
Email Address: David: DHolmes@libertyhcare.com; Timothy: TWalsh@libertyseniorliving.com
Phone Number: (910)-815-3122

Background

Liberty is an experienced family-owned company that has been helping people manage their healthcare needs for more than 145 years. The principal owners, John A. "Sandy" McNeill, Jr. and Ronnie McNeill, are proud to call North Carolina home, and are the fourth generation of McNeill's dedicated to the healthcare industry. The company founders, who opened their first pharmacy in 1875, established Liberty's core values of quality, honesty, and integrity that guide Liberty to this day.

Liberty purchased its' first nursing home in 1990 and has since expanded and worked tirelessly to provide residents with high quality levels of care through a broad range of healthcare services. Over the last three decades, Liberty has expanded its' operations from a single nursing home to become a fully integrated post-acute healthcare provider. Today, Liberty owns, operates, or manages thirty-seven nursing homes, eight assisted living facilities, two independent living communities, six Continuing Care Retirement Communities, a home health and hospice company with twenty-nine locations, two long-term care pharmacies, a medical equipment and IV therapy company, a healthcare management company, a Medicare Advantage institutional special seeds plan healthcare insurance company and the original 145-year old retail pharmacy.

Liberty's philosophy remains simple: to offer the communities we serve with a complete senior care continuum, close to home and family.

2. **Statement of Requested Change**

Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty") requests for a Policy to be added to the 2023 State Medical Facilities Plan ("SMFP"), Policy ESRD-4, which will allow for the development or expansion of a kidney disease treatment

center at a skilled nursing facility. Liberty has provided the proposed language associated with Policy ESRD-4 in Attachment 1.

3. **Reasons for the Proposed Change**

Liberty recognizes the long-standing opportunity to submit petitions to the Acute Care Services Committee and the State Health Coordinating Council ("SHCC") for requests for changes to the SMFP that have the potential for a statewide effect, such as the addition, deletion or revision of policies or need determination methodologies. Liberty wants to be clear that this proposed policy is not intended to displace outpatient dialysis facilities in the community. Liberty sees a need for the delivery of dialysis services in both environments. After careful assessment, Liberty has determined that there are unique circumstances throughout the state, specifically in nursing homes, that necessitate the new End-Stage Renal Disease ("ESRD") Policy proposed. Approval of this petition will provide Liberty and other nursing facilities ("NF's") throughout the State the opportunity to submit a Certificate of Need ("CON") application to help address the needs of a growing nursing home population.

Liberty justifies the proposed new Policy based on several factors, including:

- Advancing American Kidney Health initiative
- Basic Principles outlined in Chapter 9 of the SMFP
- Innovative dialysis technology
- CKD and ESRD most common in people aged 65 years and older
- Transportation to outpatient (offsite) dialysis clinics are challenging for nursing home facilities and residents
- Unsustainable contracting models with dialysis centers
- CON regulation of dialysis in other states
- Liberty Dialysis Experience

Advancing American Kidney Health initiative

In 2019, the Administration launched the Advancing American Kidney Health Initiative, which was designed to advance American kidney health. As part of the Initiative, the President introduced Executive Order 13879, which directed the Department of Human Services ("HHS") to take bold action to transform how kidney disease is prevented, diagnosed, and treated within the next decade. The Policy of this Executive Order stated (in part) the following goals:

a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;
b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys.

A new Policy to the SMFP allowing the development or expansion of a kidney disease treatment center at a skilled nursing facility will help meet the goals set forth in the Executive Order.

Additionally, the Advancing American Kidney Health initiative has an ambitious goal to see 80 percent of new ESRD patients either start on home dialysis or receive a preemptive transplant by 2025.

As will be detailed throughout this Petition, the nursing home dialysis model approach will help facilitate the current nursing home need for in-house dialysis care, which would directly meet the Advancing American Kidney Health initiative.

Basic Principles outlined in Chapter 9 of the SMFP

The Basic Principles of Chapter 9, End-Stage Renal Disease Dialysis Facilities, of the 2022 SMFP provides as follows:

"Basic Principles

1. New facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care.
2. **As a means of making ESRD services more accessible to patients, one goal of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the facility**. Therefore, end-stage renal disease treatment should be available within 30 miles from the patients' homes. In areas where it is apparent that patients currently travel more than 30 miles for in-center dialysis, proposed new facilities that would serve patients who are farthest away from operational or approved facilities should receive favorable consideration.
3. **The State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for: home training and backup for facility-based patients suitable for home dialysis or in a facility that is a reasonable distance from the patient's residence**; ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules; and services in rural areas."

Similar 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, and therefore would request to waive the requirement for a new dialysis facility to have at least 10 stations.

As will be discussed throughout this Petition, allowing for the development or expansion of a kidney disease treatment center at a skilled nursing facility helps meet the Basic Principles that are set forth in the SMFP, which include making ESRD services more accessible to patients as well as encouraging home dialysis that is a reasonable distance from the patient's residence.

Innovative dialysis technology

If this Petition is approved, Liberty plans to ensure the highest quality of care is being provided to nursing home ESRD patients using leading edge technology.

Liberty plans to use a state-of-the-art dialysis machine, which is designed to offer a better experience for patients and providers. As an innovative technology, the machine comes with the following features:

1. Wireless Connectivity, which allows for two way data communication to automatically send treatment data to the cloud, facilitating the efficient sharing of information with the patient's medical team;

2. Treatment modalities, which allow flexible renal replacement therapy options including extended therapy (XT), sustained low-efficiency dialysis (SLED), intermittent hemodialysis (IHD), and ultrafiltration (UF) only;
3. Touchscreen Guidance, which comes with animations and conversational instructions for a user-friendly experience;
4. Cart which is specifically designed to cut down on set-up and takedown time by removing manual steps;
5. Sensor-based automation, which helps to automate much of the setup, treatment, management, and maintenance of the machine;
6. Dialysate on demand, which purifies water and produces dialysate in real-time;
7. Mobility, as all that is required is an electrical outlet and tap water;
8. Automatic, regular updates to activate new capabilities and feature enhancements, which ensures that patients and providers have access to the latest optimizations without the need to replace existing hardware.
9. Flexible treatment duration, which can range anywhere from 30 minutes to 24 hours with no supply changeover;
10. Automated self-clean;
11. Integrated blood pressure cuff;
12. Schedule saline flush;
13. One-touch rinse back; and
14. Compatibility with high-flux dialyzers;

Through use of these designs and features, a nursing home may deliver efficient and cost-effective treatment through:

- Ease of use and reduced clinical training requirements for the equipment;
- Lower product costs than other currently available technology; and
- Use of safe tap water, eliminating reliance on expensive water treatment facilities.

The leading-age equipment would be able to offer an innovative technological approach that delivers high-quality dialysis treatment through simplified processes in a cost-efficient way.

CKD and ESRD most common in people aged 65 years and older

The Centers for Disease Control and Prevention ("CDC") has identified that chronic kidney disease ("CKD") affects 15% of US adults. In people age 65 and older, that prevalence is 38%[1]. Critically, according to the CDC National Center for Health Statistics, 83.5%[2] of nursing home residents are 65 years of age or older.

ESRD is the final, permanent stage of chronic kidney disease, where kidney function has declined to the point that the kidneys can no longer function on their own. A patient with end-stage renal failure must receive dialysis or kidney transplantation in order to survive for more than a few

[1] https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fkidneydisease%2Fpublications-resources%2F2019-national-facts.html

[2] https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf

weeks. As of 2019, 809,103 people in the U.S. were living with end-stage renal disease[3]. Almost 43% of ESRD patients are 65 or older[4].

With nearly four in ten seniors affected by chronic kidney disease and 43% of ESRD patients being 65 and older, many skilled nursing patients are or will be in need of dialysis. However, traveling to offsite dialysis can be very disruptive to the health and welfare of this population, most of whom are already frail and often have multiple health problems. The intent of the proposed policy will 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 center disrupting patient care, meals and comfort.

Transportation to outpatient (offsite) dialysis clinics are challenging for nursing home facilities and residents

Providing quality of care for all residents, inclusive of a positive dialysis treatment experience, is Liberty's number one priority. Additionally, the cost of providing these services must also be taken into account. Many of Liberty's nursing homes have their own in-house transportation to drive residents to appointments. For those residents who are wheelchair-bound or who can ambulate freely, Liberty is able to transport these individuals to and from their dialysis appointment. When in-house transportation is not available, or if a resident needs to be transported via stretcher, Liberty contracts with Non-Emergency Medical Transportation ("NEMT") operators for transportation. Given that nursing home patients typically have multiple co-morbidities, a NEMT ambulatory service is usually the preferred method of transport. For Liberty, the average cost of providing ambulatory transportation to an outpatient dialysis may cost up to $200 per round trip. With dialysis being performed 3 times per week, the cost is significant.

Nationwide staffing shortages, especially where operating in rural areas, impacts the availability of both in-house and outside transportation providers. This has significantly burdened nursing homes, and in some cases, nursing homes are unable to accept resident admissions due to the unavailability of transportation.

Perhaps most importantly, and as discussed in further detail below, the dialysis transport and off-site dialysis is disruptive and time-consuming. Typically, the transport and off-site dialysis causes residents to miss scheduled treatments and therapies/rehab, meals, medications, and family visits. Moreover, off-site dialysis causes additional exposures and, therefore, infection risks for COVID-19 and other illnesses for an already highly vulnerable patient group.

This proposal is effective for residents and nursing home operators, with transportation risks and costs greatly reduced while offering better coordination of care and a much improved patient experience.

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[3] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities (Table 1.2)

[4] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities (Figure 1.10)

Unsustainable contracting models with dialysis centers
Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare. According to a memo from CMS regarding home dialysis services in a Long Term Care (LTC) Facility, residents of a nursing home may receive chronic dialysis treatments through two options:

1. In-Center Dialysis: This may involve either:
    a. Transporting the resident to and from an off-site certified ESRD facility for dialysis treatments; or
    b. Transporting the resident to a location within or proximate to the nursing home building which is separately certified as an ESRD facility providing in-center dialysis.

2. Home Dialysis in a Nursing Home: The resident receives dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for qualifications, training, and competency verification as stated in this guidance and are provided under the auspices of a written agreement between the nursing home and the ESRD facility.

Under normal circumstances, development of an outpatient dialysis facility at a nursing facility in North Carolina would require a county need determination. However, county need determinations are very rare. Therefore, the only way nursing home residents may receive dialysis treatments would be to either have the NF transport the resident to and from an off-site ESRD facility or to have the resident receive dialysis treatment in the nursing home by a currently certified ESRD facility. We have previously detailed the difficult patient circumstances and costs related to traveling to offsite dialysis. Consequently, the only true current alternative would be to contract with dialysis providers to provide the dialysis treatments in the nursing home. Accordingly, Liberty has had discussions with providers and were, disappointingly, offered terms that are not economically viable and even financially exploitative.

The intent of the proposed policy is to enable nursing homes to be reimbursed for providing outpatient or home dialysis to patients that are better suited to being served in the nursing home. To receive Medicare reimbursement for outpatient dialysis, the Centers for Medicare and Medicaid Services ("CMS") requires that the nursing home[5] own the outpatient dialysis facility.

CON regulation of dialysis facilities in other states
Per communications with Azzie Conley, Chief of the Acute and Home Care Licensure and Certification Section, there are currently no outpatient dialysis stations located within a nursing home in North Carolina. The development of an outpatient dialysis clinic at the nursing facility would require a rarely issued county need determination.

[5] An independently certified End-Stage Renal Disease ("ESRD") facility may be located within or proximal to an independently certified nursing home. Each facility is responsible for meeting the Medicare conditions or requirements for Medicare participation for the specific provider/supplier type and would be separately surveyed. Therefore, the certified ESRD facility must be owned by the same individual or parent company as the nursing home.

Therefore, Liberty analyzed other CON states to review whether the nursing home dialysis model works. Currently, thirty-five (35) states operate a CON program, with variations state to state. Of the thirty-five (35) CON states, only eleven (11) have some form of CON program that regulates kidney disease treatment centers (including North Carolina). Liberty believes it is important to note that the three (3) states contiguous to North Carolina (South Carolina, Tennessee, and Virginia) are all CON states that do not regulate dialysis under their CON laws.

One of the states that is leading the nursing home dialysis model is Illinois. The Health Facilities Planning Act (the "Act") (20 ILCS 3960), established Illinois' CON program, which includes dialysis centers. The Act provides an exemption to dialysis units that are located in licensed nursing homes. The Act specific to this provides:

> 5) Kidney disease treatment centers, including a free-standing hemodialysis unit required to meet the requirements of 42 CFR 494 in order to be certified for participation in Medicare and Medicaid under Titles XVIII and XIX of the federal Social Security Act.
>
> (A) This Act does not apply to a dialysis facility that provides only dialysis training, support, and related services to individuals with end stage renal disease who have elected to receive home dialysis.
>
> **(B) This Act does not apply to a dialysis unit located in a licensed nursing home that offers or provides dialysis-related services to residents with end stage renal disease who have elected to receive home dialysis within the nursing home.**
>
> (C) The Board, however, may require dialysis facilities and licensed nursing homes under items (A) and (B) of this subsection to report statistical information on a quarterly basis to the Board to be used by the Board to conduct analyses on the need for proposed kidney disease treatment centers.

To qualify under the Illinois statute, a nursing home must provide the Illinois Health Facilities and Services Review Board an exemption request that includes the name and address of the long-term care facility, the number of stations requested, who will be operating the stations, and the cost. The nursing home will then receive an approval letter back stating a CON is not needed.

According to The United States Renal Data System ("USRDS"), Illinois is the leading provider of home hemodialysis, in which 4.6% of patients with ESRD utilized in-home hemodialysis[6]. All other state and Network (as defined in the USRDS report) rates of ESRD patients who performed in-home hemodialysis varied between 0.5% and 2.0%. According to the USRDS, "this outlying value is likely attributable to a large population of skilled nursing facility residents utilizing on-site hemodialysis, which is indistinguishable from home dialysis in claims." This Policy would allow North Carolina to join Illinois at the forefront of providing dialysis services for this special

[6] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

nursing home patient population within the nursing home, which will directly correlate to an increase in home dialysis.

Liberty Dialysis Experience

The current permitted structure for dialysis treatment for nursing facility residents does not allow Liberty facilities to provide optimal quality health care services to the residents and communities Liberty serves.

Currently, twenty-seven (27) of Liberty's nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents. We spoke with our communities and some of the quotes point to the significance this Policy would have on the nursing home dialysis resident.

On the importance of maintaining continued quality care: "We have a good plan of action to support residents while they are in our facility. However, when they leave to go out for the day – and that day may be a full eight hours or more – when they come back, they are at a different level of distress. They might have been sitting in their soiled undergarments all day and they may have been without food for a period of time. It would be great if we had a program that would keep them in-house because it would be able to afford the resident a continued quality of care. The same dedicated staff would be with them from the beginning to the end of their day. They would have their ADLs (activities of daily living) taken care of and they would have their nourishment through meals and snacks while they are resting comfortably in their room surrounded by all the things that bring them peace and comfort while in our care." – Charles Duff, Administrator

On the physical toll it takes on residents: "It's a draining process, literally. When they come back six or more hours later, they are wiped out. The core of dialysis is cleaning the blood, so any time there is filtering of the blood, it's exhausting for them. Sometimes we can't get them back to the facility right when they are done because we may have another transport. It feels like an all-day process for us. I can't even imagine what it feels like for them." – Terri King, RN, Director of Nursing

On how dialysis affects a resident's therapy program: "Typically, our patients have dialysis three times a week. We try to do therapy five days a week. A lot of times we run into difficulty working with the patients because of their dialysis times. We also run into smaller windows of time where we are able to work with them on dialysis days. If a patient has dialysis at 10 o'clock in the morning, we are trying to get occupational, physical and sometimes speech therapy to see that person prior to going out. That is sometimes difficult if you have someone who has a low activity tolerance. The inability to have flexibility with patients who are going out for dialysis is often a problem. Sometimes I will have someone come in the afternoon, say a PRN therapist, and if the patient is out for dialysis they are unable to be seen. It affects their ability to participate in therapy. Typically, they are wiped out afterwards so we might not get as much out of them when they come back that day." – Michael Write, Occupational Therapist

The consistent theme of these statements is that the current structure for nursing home dialysis residents is unpleasant and punishing for them. The vast majority of nursing home residents needing dialysis cannot transport themselves. For the resident, the ride is disruptive, confusing and

time-consuming. Many times, this causes residents to miss their scheduled and necessary treatments, therapies/rehab, meals, medications, and family visits. This proposal would allow residents to continue receiving their necessary care, treatments and therapy while their dialysis schedule is integrated into the resident's care, treatment and therapy needs. Residents would no longer miss meals and medications or family visits. The dialysis and nursing home teams will work collaboratively to ensure that the care of each patient is consistent and individualized.

a. Statement of the Adverse Effects if Change Not Made

If this Petition is not approved, dialysis options for nursing home residents will continue to be limited, specifically in ways that are not beneficial or easily accessible to nursing facility residents or economically affordable for nursing facilities. The residents requiring dialysis treatments would need to continue disruptive transportation and lengthy off-site dialysis center treatments, causing residents to miss scheduled treatments, therapy, meals, medications, and family visits while continuing to place the transportation cost burden on nursing home operators.

b. Statement of Alternatives to the Proposed Change

Liberty has discussed several possible alternatives. These included:

1. Petition for adjusted need determination in specific service area(s)
2. Include ACH facilities in proposed Policy ESRD-4 Policy

Petition for adjusted need determination in specific service area(s)

Liberty considered petitioning for an adjusted need determination in specific service areas/counties, as current county need determinations in the SMFP are very rare. However, this approach is problematic. The need for outpatient dialysis stations at nursing homes is not based on just one specific county or even just a few counties. These troubling circumstances are statewide, specifically in nursing homes, which necessitate a new ESRD Policy as opposed to specific county need determinations.

Additionally, a county need determination would not be bound to meet the exclusive situation for outpatient dialysis stations within the nursing home. A county need determination would allow an established or new outpatient dialysis provider to potentially apply and win the Certificate of Need, which would then defeat the purpose of this Petition's intent.

Include ACH facilities in proposed Policy ESRD-4 Policy

As discussed on page 1, Liberty is an experienced healthcare provider, as it currently owns, operates, or manages thirty-seven nursing homes and eight assisted living facilities. Therefore, Liberty also considered if including adult care home ("ACH") facilities to the proposed Policy ESRD-4 Policy would be beneficial to residents. It was determined that the vast majority of ACH residents are still able to travel to outpatient dialysis facilities within the community with less harmful disruption to daily needs and routines, as these residents are still active and oftentimes do not have the multiple health problems nursing home residents face.

The needs of nursing home residents with dialysis are not being met or are being met in ways that are not the most beneficial to residents or cost-effective. Therefore, Liberty determined that the policy proposed (ESRD-4) by this petition is the most effective way to provide dialysis treatment for nursing home residents.

4. **Evidence Proposed Change Would Not Result in Unnecessary Duplication of Health Resources in the Area**

Since there are currently no outpatient dialysis stations located within a nursing home in North Carolina, this proposed policy is not intended to replace outpatient dialysis facilities in the community. Currently, ESRD services have two methodologies to determine the need for a CON: (i) the county need methodology which projects need for the county; and (ii) the facility need methodology which projects need for a specific facility. When a county need determination exists, any qualified applicant may apply to add stations in an existing facility or apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations. Liberty proposes to exclude existing and newly developed outpatient dialysis facilities in a nursing home from the county and specific facility need determination methodologies. Therefore, current outpatient dialysis facilities or county need projects will remain unaffected by this proposal.

The proposed policy will not result in an unnecessary duplication of services. Instead, the proposed policy will serve to expand access to dialysis services for special nursing home patient populations that are otherwise underserved or served in sub-optimal conditions and settings.

5. **Evidence Requested Change is Consistent with Three Basic Principles Governing the Development of the SMFP (Safety and Quality, Access and Value)**

The requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: (i) Safety and Quality, (ii) Access and (iii) Value.

Safety and Quality
Liberty agrees with the State of North Carolina and the SMFP's acknowledgement of "the importance of systematic and ongoing improvement in the quality of health services." Additionally, the SHCC "recognizes that while safety, clinical outcomes, and satisfaction may be conceptually separable, they are often interconnected in practice." This proposal maximizes all three elements:

Safety: This proposal would allow residents more time for treatments, therapies, meals, family time, and social activities while decreasing the risk of infection and complications associated with offsite travel.

Clinical outcomes: This proposal would allow residents needing nursing and therapy services to receive their care while their dialysis schedule is adjusted around the resident's nursing and therapy. Residents would no longer miss meals and medications. The dialysis team and the nursing

home team will work collaboratively to ensure that the care of each patient is consistent and individualized.

Satisfaction: With transportation risks eliminated and more time for treatments, therapies, meals, family time, and social activities, this proposal would maximize satisfaction of dialysis nursing home residents.

Access
Liberty fully supports the principle of "equitable access to timely, clinically appropriate and high-quality health care for all the people of North Carolina." As discussed above, this new model approach will facilitate the current nursing home need for in-house dialysis care, greatly improving patient access to care consistent with this principle. The SMFP states, "the formulation and implementation of the Plan seeks to reduce all of these types of barriers to timely and appropriate access. The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers."

Approval of this Petition results in both priorities being met. As discussed in the SMFP, a competitive marketplace should favor providers that deliver the highest quality and best value care, but only in the circumstances where all competitors deliver like services to similar population. In this instance, the services would be provided to a similar population (ESRD patients), and the nursing home can deliver the highest quality and best value of care by eliminating transportation risks and costs as well as better collaboration of care and greater comfort and service for the residents. This policy would additionally mitigate time and distance barriers, as it would allow the care to happen onsite (or at home through bedside care), which would eliminate the time and distance barriers.

Value
Liberty additionally agrees with SHCC to "encourage the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care. The SHCC also recognizes the importance of balanced competition and market advantage in order to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery." This added Policy to the SMFP would permit better collaboration of care, fewer hospital readmissions, a stronger relationship with hospital and dialysis partners (through referrals of high acuity residents), while also eliminating the associated high transportation costs.

Conclusion
Liberty again wants to make certain, it is not the intent to use the proposed policy to supplant outpatient dialysis facilities in the community. Liberty sees a need for both. Approval of this Petition will provide Liberty and other SNF's throughout the State the opportunity to develop or expand kidney disease treatment centers at skilled nursing facilities for the benefit of ESRD residents.

ATTACHMENT 1

PROPOSED POLICY ESRD-4

Policy ESRD-4: Development or Expansion of a Kidney Disease Treatment Center in a Nursing Home

Licensed nursing homes (see stipulations in 131E-102 (e1)) may apply for a certificate of need to develop or expand an existing Medicare-certified kidney disease treatment center (outpatient dialysis facility) without regard to a county or facility need determination if all the following are true:

1. The nursing home proposes to develop or expand the facility on any campus on its license where nursing home beds are located.
2. The nursing home must own the outpatient dialysis facility*, but the nursing home may contract with another legal entity to operate the facility.
3. The nursing home must document that the patients it proposes to serve in an outpatient dialysis facility developed or expanded pursuant to this policy are appropriate for treatment in an outpatient dialysis facility located in a nursing home.
4. The nursing home must establish a relationship with a hospital-based dialysis facility (where applicable) to assist in the transition of patients from the hospital dialysis facility to the nursing home facility wherever possible.

*An independently certified End-Stage Renal Disease ("ESRD") facility may be located within or proximal to an independently certified nursing home. Each facility is responsible for meeting the Medicare conditions or requirements for Medicare participation for the specific provider/supplier type and would be separately surveyed. Therefore, the certified ESRD facility must be owned by the same individual, parent or affiliated company as the nursing home.

The nursing home shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare & Medicaid Services (CMS). Certificate of Need will impose a condition requiring the nursing home to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.

The performance standards in 10A NCAC 14C .2203 do not apply to a proposal submitted by a nursing home pursuant to this policy.

Dialysis stations developed pursuant to this policy are excluded from the inventory in the State Medical Facilities Plan and excluded from the facility and county need methodologies.

Outpatient dialysis facilities developed or expanded pursuant to this policy shall report utilization to the Agency in the same manner as other facilities with outpatient dialysis stations.

Exhibit B

EXHIBIT
tabbies
B

Liberty Healthcare
& Rehabilitation Services
Caring with Excellence
2334 S. 41st Street • Wilmington, NC 28403
(910) 815-3122 • FAX: (910) 815-3111

PETITION FOR ADJUSTED FACILITY NEED DETERMINATION FOR NURSING HOME DIALYSIS PILOT DEMONSTRATION PROJECT IN MECKLENBURG COUNTY IN THE 2023 STATE MEDICAL FACILITIES PLAN

1. Name, address, email address, and phone number of the Petitioner:

Name: Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty")
ATTN: David Holmes, Vice President of Business Development and Timothy Walsh, Director of Business Development
Address: 2334 S 41st Street, Wilmington, NC 28451
Email Address: David: DHolmes@libertyhcare.com; Timothy: TWalsh@libertyseniorliving.com
Phone Number: (910)-815-3122

Background

Liberty is an experienced family-owned company that has been helping people manage their healthcare needs for more than 145 years. The principal owners, John A. "Sandy" McNeill, Jr. and Ronnie McNeill, are proud to call North Carolina home, and are the fourth generation of McNeill's dedicated to the healthcare industry. The company founders, who opened their first pharmacy in 1875, established Liberty's core values of quality, honesty, and integrity that guide Liberty to this day.

Liberty built its first nursing home in 1994 and has since expanded and worked tirelessly to provide residents with high quality levels of care through a broad range of healthcare services. Over the last three decades, Liberty has expanded its' operations from a single nursing home to become a fully integrated post-acute healthcare provider. Today, Liberty owns, operates, or manages thirty-seven nursing homes, eight assisted living facilities, two independent living communities, six Continuing Care Retirement Communities, a home health and hospice company with twenty-nine locations, two long-term care pharmacies, a medical equipment and IV therapy company, a healthcare management company, a Medicare Advantage institutional special seeds plan healthcare insurance company and the original 145-year old retail pharmacy.

Liberty's philosophy remains simple: to offer the communities we serve a complete senior care continuum, close to home and family.

2. Statement of Requested Change

Long Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty") respectfully requests the addition of a need for a nursing home dialysis pilot demonstration project of six outpatient dialysis stations in Mecklenburg County in the 2023 State

Medical Facilities Plan ("SMFP"). This would represent a modification to Chapter 9 of the SMFP, and specifically to Chapter 9D, which would include the following:

Table 9D: Dialysis Station Need Determination by Facility

A	B	C	D	E
County	**Facility Identification Number**	**Provider Number**	**Facility**	**Facility Station Need Determination**
Mecklenburg	TBD	TBD	Royal Park of Matthews	6**

***In response to a petition from Liberty on behalf of Royal Park of Matthews, the State Health Coordinating Council approved an adjusted need determination for six dialysis stations in Mecklenburg County to be included in a demonstration nursing home-only dialysis facility. This is a nursing home dialysis demonstration pilot project that is in the inventory but is not included in need determination calculations.*

3. Reasons for the Proposed Change

Liberty recognizes the long-standing opportunity to submit petitions to the Acute Care Services Committee and the State Health Coordinating Council ("SHCC") for requests for changes to the SMFP that have the potential for a statewide effect, such as the addition, deletion or revision of policies or need determination methodologies. Liberty wants to be clear that this proposed demonstration project is not intended to displace outpatient dialysis facilities in the community. Liberty sees a need for the delivery of dialysis services in both environments. After careful assessment, Liberty has determined that there are unique circumstances that necessitate this proposed new End-Stage Renal Disease ("ESRD") facility demonstration project. Approval of this petition will provide Liberty the opportunity to submit a Certificate of Need ("CON") application pursuant to the facility need methodology.

Liberty requests the proposed facility need determination based on several factors, including:

- Advancing American Kidney Health initiative
- Basic Principles outlined in Chapter 9 of the SMFP
- Innovative dialysis technology
- CKD and ESRD most common in people aged 65 years and older
- Transportation to outpatient (offsite) dialysis clinics are challenging for nursing home facilities and residents
- Difficulty hospitals face in finding placement for high acute residents including seniors needing dialysis services
- Unsustainable contracting models with dialysis centers
- CON regulation of dialysis in other states
- Liberty Dialysis Experience

Advancing American Kidney Health initiative

In 2019, the Federal government launched the Advancing American Kidney Health Initiative, which was designed to advance American kidney health. As part of the Initiative, the President signed Executive Order 13879, which directed the U.S. Department of Health & Human Services ("HHS") to take bold action to transform how kidney disease is prevented, diagnosed, and treated within the next decade. The Executive Order identified the following goals, among others:

a) prevent kidney failure whenever possible through better diagnosis, treatment, and incentives for preventive care;
b) increase patient choice through affordable alternative treatments for ESRD by encouraging higher value care, educating patients on treatment alternatives, and encouraging the development of artificial kidneys.

A nursing home dialysis pilot demonstration project of six outpatient dialysis stations in Mecklenburg County allowing the development or expansion of a kidney disease treatment center at Royal Park of Matthews will help meet the goals set forth in the American Kidney Health Initiative.

Basic Principles outlined in Chapter 9 of the SMFP

The Basic Principles of Chapter 9, End-Stage Renal Disease Dialysis Facilities, of the 2022 SMFP provide as follows:

"Basic Principles

1. New facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care.
2. **As a means of making ESRD services more accessible to patients, one goal of the N.C. Department of Health and Human Services is to minimize patient travel time to and from the facility**. Therefore, end-stage renal disease treatment should be available within 30 miles from the patients' homes. In areas where it is apparent that patients currently travel more than 30 miles for in-center dialysis, proposed new facilities that would serve patients who are farthest away from operational or approved facilities should receive favorable consideration.
3. **The State Health Coordinating Council encourages applicants for dialysis stations to provide or arrange for: home training and backup for facility-based patients suitable for home dialysis or in a facility that is a reasonable distance from the patient's residence**; "ESRD dialysis service availability at times that do not interfere with ESRD patients' work schedules; and services in rural areas."

Royal Park of Matthews has the necessary infrastructure to house outpatient dialysis stations, and therefore would requests a waiver of the SMFP requirement that a new dialysis facility have at least 10 stations. We believe that requirement was based on the presumed size (*i.e.,* number of dialysis stations) needed to make a new ESRD center viable, a concern not present in the proposed demonstration project which would be housed in an existing, viable skilled nursing facility.

A nursing home dialysis pilot demonstration project for six outpatient dialysis stations in Mecklenburg County allowing the development of a kidney disease treatment center at Royal Park of Matthews helps meet the Basic Principles that are set forth in the SMFP, which include making

ESRD services more accessible to patients as well as encouraging home dialysis that is a reasonable distance from the patient's residence.

Innovative dialysis technology
If this Petition is approved, Liberty plans to ensure the highest quality of care is being provided to nursing home ESRD patients using leading edge technology.

Liberty plans to use a state-of-the-art Tablo dialysis machine, which is designed to offer a better experience for patients and providers. As an innovative technology, the machine comes with the following features:

1. Wireless Connectivity, which allows for two-way data communication to automatically send treatment data to the cloud, facilitating the efficient sharing of information with the patient's medical team;
2. Treatment modalities, which allow flexible renal replacement therapy options including extended therapy (XT), sustained low-efficiency dialysis (SLED), intermittent hemodialysis (IHD), and ultrafiltration (UF) only;
3. Touchscreen Guidance, which comes with animations and conversational instructions for a user-friendly experience;
4. Cart which is specifically designed to cut down on set-up and takedown time by removing manual steps;
5. Sensor-based automation, which helps to automate much of the setup, treatment, management, and maintenance of the machine;
6. Dialysate on demand, which purifies water and produces dialysate in real-time;
7. Mobility, as all that is required is an electrical outlet and tap water;
8. Automatic, regular updates to activate new capabilities and feature enhancements, which ensures that patients and providers have access to the latest optimizations without the need to replace existing hardware.
9. Flexible treatment duration, which can range anywhere from 30 minutes to 24 hours with no supply changeover;
10. Automated self-clean;
11. Integrated blood pressure cuff;
12. Schedule saline flush;
13. One-touch rinse back; and
14. Compatibility with high-flux dialyzers;

Through use of these designs and features, Royal Park of Matthews will be able to deliver efficient and cost-effective treatment through:

- Ease of use and reduced clinical training requirements for the equipment;
- Lower product costs than other currently available technology; and
- Use of safe tap water, eliminating reliance on expensive water treatment facilities.

The leading-age equipment would be able to offer an innovative technological approach that delivers high-quality dialysis treatment through simplified processes in a cost-efficient way.

CKD and ESRD most common in people aged 65 years and older

The Centers for Disease Control and Prevention ("CDC") has identified that chronic kidney disease ("CKD") affects 15% of US adults. In people age 65 and older, that prevalence is 38%[1]. According to the CDC National Center for Health Statistics, 83.5%[2] of nursing home residents are 65 years of age or older.

ESRD is the final, permanent stage of chronic kidney disease, where kidney function has declined to the point that the kidneys can no longer function on their own. A patient with end-stage renal failure must receive dialysis or kidney transplantation in order to survive for more than a few weeks. As of 2019, 809,103 people in the U.S. were living with end-stage renal disease[3]. Almost 43% of ESRD patients are 65 or older[4].

With nearly four in ten seniors affected by chronic kidney disease and 43% of ESRD patients being 65 and older, many skilled nursing patients are or will be in need of dialysis. However, traveling to offsite dialysis can be very disruptive to the health and welfare of this population, most of whom are already frail and often have multiple health problems. The goal of the proposed nursing home dialysis pilot demonstration project is to enable Royal Park of Matthews to meet the needs of this vulnerable population safely while simultaneously eliminating the need for uncomfortable patient transports, lengthy patient wait times at community dialysis centers and treatments at off-site dialysis center which disrupt patient care, meals, socialization and comfort.

Transportation to outpatient (offsite) dialysis clinics is challenging for Royal Park of Matthews and residents

Providing quality of care for all residents, inclusive of a positive dialysis treatment experience, is Liberty's number one priority. Additionally, the cost of providing these services must also be taken into account. Royal Park of Matthews contracts with Non-Emergency Medical Transportation ("NEMT") operators for transportation. Given that nursing home patients typically have multiple co-morbidities, a NEMT ambulance service is usually the preferred method of transport. For Royal Park of Matthews, the average cost of providing ambulance transportation to an outpatient dialysis clinic may be up to $104 per round trip. With dialysis being performed a minimum of 3 times per week, the cost is significant. For example, one long-term resident requiring dialysis 3 times per week (for 52 weeks) would total $16,224 per year just in transportation costs. There is no reimbursement mechanism for these transports, and, depending on the payor source, these costs fall directly on the nursing facility.

Nationwide staffing shortages, especially where operating in rural areas, impacts the availability of both in-house and outside transportation providers. This has significantly burdened nursing homes, and in some cases, nursing homes are unable to accept resident admissions due to the unavailability of transportation.

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[1] https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fkidneydisease%2Fpublications-resources%2F2019-national-facts.html

[2] https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf

[3] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities (Table 1.2)

[4] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities (Figure 1.10)

Perhaps most importantly, and as discussed in further detail below, the dialysis transport and off-site dialysis is disruptive and time-consuming. Typically, the transport and off-site dialysis causes residents to miss scheduled treatments and therapies/rehab, meals, medications, and family visits. Moreover, off-site dialysis causes additional exposures and, therefore, infection risks for COVID-19 and other illnesses for an already highly vulnerable patient group.

This proposal is effective and beneficial for residents and nursing home operators, with transportation risks and costs greatly reduced while offering better coordination of care and a much improved patient experience.

Difficulty hospitals face finding placement for high acute residents
Oftentimes, hospitals struggle to find placement at outpatient centers for high acuity residents needing dialysis. Many skilled nursing communities cannot accept these higher acuity residents due to the travel demands to and cost associated with community based dialysis centers, and the outpatient centers are unable to support patients with multiple comorbidities. Therefore, upon discharge from the dialysis center, these residents end up being readmitted to the hospital.

Having the availability to discharge patients with dialysis needs to a nursing home and have one facility address both skilled and dialysis care would be a clinical innovation. Same-location care would allow for safe delivery of dialysis services, better collaboration of care, fewer hospital readmissions, and stronger relationships between nursing home operators and hospitals. As noted above, it would also reduce or eliminate a number of well-known risks attendant to frequent travel from nursing homes to community-based dialysis centers including loss of patient routine and socialization opportunities; infections; bodily wear-and-tear; and van or ambulance accidents; among others.

Unsustainable contracting models with dialysis centers
Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare. According to a memo from CMS regarding home dialysis services in a Long Term Care (LTC) Facility, residents of a nursing home may receive chronic dialysis treatments through two options:

1. In-Center Dialysis: This may involve either:
    a. Transporting the resident to and from an off-site certified ESRD facility for dialysis treatments; or
    b. Transporting the resident to a location within or proximate to the nursing home building which is separately certified as an ESRD facility providing in-center dialysis.

2. Home Dialysis in a Nursing Home: The resident receives dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for qualifications, training, and competency verification as stated in this guidance and are provided under the auspices of a written agreement between the nursing home and the ESRD facility.

Currently, under the existing SMFP, development of an outpatient dialysis facility at a nursing facility in North Carolina would require that there be a county need determination in the county where a nursing home wishing to develop such a program is located. However, county need determinations are very rare and have been for many years. Therefore, the only way nursing home residents can receive dialysis treatments is for the resident to be transported to an off-site ESRD facility or to have the resident receive dialysis treatment in the nursing home by a currently-certified ESRD facility. We have previously detailed the difficult patient circumstances and costs related to traveling to offsite dialysis centers. Consequently, the only true current alternative would be to contract with dialysis providers to provide the dialysis treatments in the nursing home. Accordingly, Liberty has had discussions with providers and were, disappointingly, offered terms that are not economically viable and were, in fact, cost-prohibitive.

One goal of the proposed pilot demonstration project is to enable Royal Park of Matthews to be reimbursed for providing outpatient or home dialysis to patients that are better suited to being served in the nursing home. The project will also demonstrate, consistent with similar experiences in other states, that dialysis can be provided to nursing home residents safely, cost-effectively and in an environment much more comfortable and familiar to these vulnerable seniors. To receive Medicare reimbursement for outpatient dialysis, the Centers for Medicare and Medicaid Services ("CMS") requires that the nursing home[5] own the outpatient dialysis facility.

CON regulation of dialysis facilities in other states

Per communications with Azzie Conley, Chief of the Acute and Home Care Licensure and Certification Section, there are currently no outpatient dialysis stations located within a nursing home in North Carolina. As previously noted the development of an outpatient dialysis clinic at a nursing facility currently requires a county need determination in that county in the SMFP, which almost never exists. As such, without a special need determination, as requested in this Petition, N.C. nursing homes will never be able to follow a growing national trend based on the model Liberty is requesting permission to demonstrate.

Liberty has analyzed other CON states to determine whether the nursing home dialysis model works. Currently, thirty-five (35) states operate a CON program, with variations from state to state. Of the thirty-five (35) CON states, only eleven (11) have some form of CON program that regulates kidney disease treatment centers (including North Carolina). Liberty believes it is important to note that the three (3) states contiguous to North Carolina (South Carolina, Tennessee, and Virginia) are all CON states that do not regulate dialysis under their CON laws.

One of the states that is leading the nursing home dialysis model is Illinois. The Health Facilities Planning Act (the "Act") (20 ILCS 3960), established Illinois' CON program, which includes dialysis centers. The Act provides an exemption to dialysis units that are located in licensed nursing homes. The Act specific to this provides:

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[5] An independently certified End-Stage Renal Disease ("ESRD") facility may be located within or proximal to an independently certified nursing home. Each facility is responsible for meeting the Medicare conditions or requirements for Medicare participation for the specific provider/supplier type and would be separately surveyed. Therefore, the certified ESRD facility must be owned by the same individual or parent company as the nursing home.

5) Kidney disease treatment centers, including a free-standing hemodialysis unit required to meet the requirements of 42 CFR 494 in order to be certified for participation in Medicare and Medicaid under Titles XVIII and XIX of the federal Social Security Act.

(A) This Act does not apply to a dialysis facility that provides only dialysis training, support, and related services to individuals with end stage renal disease who have elected to receive home dialysis.

(B) This Act does not apply to a dialysis unit located in a licensed nursing home that offers or provides dialysis-related services to residents with end stage renal disease who have elected to receive home dialysis within the nursing home.

(C) The Board, however, may require dialysis facilities and licensed nursing homes under items (A) and (B) of this subsection to report statistical information on a quarterly basis to the Board to be used by the Board to conduct analyses on the need for proposed kidney disease treatment centers.

To qualify under the Illinois statute, a nursing home must provide the Illinois Health Facilities and Services Review Board an exemption request that includes the name and address of the long-term care facility, the number of stations requested, who will be operating the stations, and the cost. The nursing home will then receive an approval letter stating that a CON is not needed. North Carolina already has a similar CON exemptions process for certain types of health care projects and equipment.

According to The United States Renal Data System ("USRDS"), Illinois is the leading provider of home hemodialysis, with 4.6% of ESRD patients utilizing in-home hemodialysis[6]. All other states, and Network reporting dialysis utilization (as defined in the USRDS report), report rates of ESRD patients who performed in-home hemodialysis between 0.5% and 2.0%. According to the USRDS, "this outlying value is likely attributable to a large population of skilled nursing facility residents utilizing on-site hemodialysis, which is indistinguishable from home dialysis in claims." This pilot demonstration project will allow North Carolina to join Illinois at the forefront of providing dialysis services for this special nursing home patient population within the nursing home, which will directly correlate to an increase in home dialysis.

Liberty Dialysis Experience

The current SMFP and related CON limitations on dialysis treatment centers do not allow Liberty facilities to provide optimal quality health care services to the residents and communities Liberty serves by providing dialysis services in nursing homes.

Currently, twenty-seven (27) of Liberty's nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents. We spoke with Royal Parks Administrator, Director of Nursing, and Rehab Director and some of the quotes from those

[6] https://adr.usrds.org/2021/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

discussions point to the significance this pilot demonstration project would have on their nursing home dialysis residents.

On the importance of maintaining continued quality care: "An in-house dialysis program would help Royal Park maintain continued quality care for our patients by allowing the nursing staff to provide all of the necessary care and support to the patients. Additionally, by staying in-house, the patients would not have to worry about traveling to and from the dialysis center, which could be a burden for some. The in-house dialysis program would also allow Royal Park to monitor the patients' progress better and ensure they receive the best possible care. Additionally, by staying in-house, the patients would have more time to rest and recover between dialysis treatments, improving their overall well-being." – Chase Flowers, Administrator

On the physical toll it takes on residents: "The patients at Royal Park would likely have a better experience if they stayed in-house for their dialysis treatments. This is because they would be able to receive all of the necessary care and support from the nursing staff, which could improve their overall well-being. Additionally, by staying in-house, the patients would not have to worry about traveling to and from the dialysis center, which could be a burden for some." – Mary Poston, Director of Nursing

On how dialysis affects a resident's therapy program: "Dialysis can affect a patient's ability to participate in their therapy program by making them tired and weak. This can make it difficult for the patients to participate in their therapy sessions. The dialysis treatments can also be quite time-consuming, so the patients may not have enough time to do everything they need during their therapy program. However, if the patients stayed in-house for their dialysis treatments, they would be able to receive the care and support they need from the nursing staff, which could help them to participate more fully in their therapy program. Staying in-house would also allow patients more time to rest and recover between dialysis treatments, which could improve their overall health and well-being." – Melinda Butler, Rehab Director

The consistent theme of these statements is that the current community-based ESRD centers for nursing home dialysis residents is unpleasant and punishing for them. The vast majority of nursing home residents needing dialysis cannot transport themselves. For the resident, the ride is disruptive, confusing and time-consuming. Many times, this causes residents to miss their scheduled and necessary treatments, therapies/rehab, meals, medications, and family visits. This proposal would allow residents to continue receiving their necessary care, treatments and therapy while their dialysis schedule is integrated into the resident's on-site care plans. Residents would no longer miss meals and medications or family visits. The dialysis and nursing home teams will work collaboratively to ensure that the care of each patient is consistent and individualized.

a. **Statement of the Adverse Effects if Change Not Made**
   If this Petition is not approved, dialysis options for Royal Park residents will continue to be limited, specifically in ways that are not beneficial or easily accessible to Royal Park residents or economically affordable for the nursing facility. The residents requiring dialysis treatments would need to continue disruptive transportation and lengthy off-site dialysis center treatments, causing residents to miss scheduled treatments, therapy, meals, medications, and family

visits while continuing to place the transportation cost burden on the nursing home operator.

b. Statement of Alternatives to the Proposed Change

Liberty has discussed only one other alternative to the proposed change, which included:

1. Submit Spring Petition for the creation of Policy ESRD-4 to allow to for the development or expansion of a kidney disease treatment center ("outpatient dialysis facility") at a skilled nursing facility

Earlier this year, Liberty presented a Spring Petition to the State Health Coordinating Council requesting the addition of Policy ESRD-4 to the 2023 SMFP which would allow the provision of dialysis services to skilled nursing facility residents at the facility where they live rather than requiring them to be loaded onto transport vans multiple times each week and driven to a community dialysis center for treatment. The dialysis services being proposed would be provided via an approved dialysis provider and in accord with all applicable state and federal regulations governing dialysis services.

The Healthcare Planning and Certificate of Need staff recommended denial of Liberty's Petition, largely because they believed that the SMFP's existing summer petition process is sufficient to allow Liberty to develop the proposed services. The Acute Care Services Committee, while noting support for the notion that this request would be positive for North Carolina residents, voted to accept the Agency recommendation and deny the Petition. Based on those votes and that guidance, Liberty is now bringing this demonstration project before the SHCC as a Summer Petition.

Liberty has great respect for the work of the Agency staff and the SHCC and its committees, and based on the staff's and SHCC's suggestions, is moving forward with this Summer Petition for a nursing home dialysis pilot demonstration project of six outpatient dialysis stations in Mecklenburg County. Liberty believes the demonstration project proposed will demonstrate to the Agency staff and the SHCC that a program like the one being proposed will work.

4. <u>Evidence Proposed Change Would Not Result in Unnecessary Duplication of Health Resources in the Area</u>

Since there are currently no outpatient dialysis stations located within a nursing home in North Carolina, this proposed pilot demonstration project is not intended to replace outpatient dialysis facilities in the community. Currently, ESRD services have two methodologies to determine the need for a CON: (i) the county need methodology which projects need for the county; and (ii) the facility need methodology which projects need for a specific facility. When a county need determination exists, any qualified applicant may apply to add stations in an existing facility or apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations. Liberty proposes to exclude the Mecklenburg County

nursing home dialysis demonstration pilot project from need determination calculations. Therefore, current outpatient dialysis facilities or county need projects will remain unaffected by this proposal.

The proposed pilot demonstration project will not result in an unnecessary duplication of services. Instead, the proposed pilot demonstration project will serve to expand access to dialysis services for special nursing home patient populations that are otherwise underserved or served in sub-optimal conditions and settings.

5. **Evidence Requested Change is Consistent with Three Basic Principles Governing the Development of the SMFP (Safety and Quality, Access and Value)**

The requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: (i) Safety and Quality, (ii) Access and (iii) Value.

Safety and Quality
Liberty agrees with the State of North Carolina and the SMFP's acknowledgement of "the importance of systematic and ongoing improvement in the quality of health services." Additionally, the SHCC "recognizes that while safety, clinical outcomes, and satisfaction may be conceptually separable, they are often interconnected in practice." This proposal maximizes all three elements:

Safety: This proposal would allow residents more time for treatments, therapies, meals, family time, and social activities while decreasing the risk of infection and complications associated with offsite travel.

Clinical outcomes: This proposal would allow residents needing nursing and therapy services to receive their care while their dialysis schedule is adjusted around the resident's nursing and therapy. Residents would no longer miss meals and medications. The dialysis team and the nursing home team will work collaboratively to ensure that the care of each patient is consistent and individualized.

Satisfaction: With transportation risks eliminated and more time for treatments, therapies, meals, family time, and social activities, this proposal would increase satisfaction of dialysis for nursing home residents.

Access
Liberty fully supports the principle of "equitable access to timely, clinically appropriate and high-quality health care for all the people of North Carolina." As discussed above, this new model will address the current nursing home need for in-house dialysis care, greatly improving patient access to care consistent with this principle. The SMFP states, "the formulation and implementation of the Plan seeks to reduce all of these types of barriers to timely and appropriate access. The first priority is to ameliorate economic barriers and the second priority is to mitigate time and distance barriers."

Approval of this Petition results in both priorities being met. As discussed in the SMFP, a competitive marketplace should favor providers that deliver the highest quality and best value care, but only in the circumstances where all competitors deliver like services to similar population. In this instance, the services would be provided to a similar population (ESRD patients), and the nursing home can deliver the highest quality and best value of care by eliminating transportation risks and costs as well as better collaboration of care and greater comfort and service for the residents. This pilot demonstration project would additionally mitigate time and distance barriers, as it would allow the care to happen onsite (or at home through bedside care), which would eliminate the time and distance barriers.

Value

Liberty additionally agrees with SHCC to "encourage the development of value-driven health care by promoting collaborative efforts to create common resources such as shared health databases, purchasing cooperatives, and shared information management, and by promoting coordinated services that reduce duplicative and conflicting care. The SHCC also recognizes the importance of balanced competition and market advantage in order to encourage innovation, insofar as those innovations improve safety, quality, access, and value in health care delivery." This added pilot demonstration project to the SMFP would permit better collaboration of care, fewer hospital readmissions, a stronger relationship with hospital and dialysis partners (through referrals of high acuity residents), while also eliminating the associated high transportation costs.

Conclusion

Liberty again stresses that there is no intention to use the proposed pilot demonstration project to replace outpatient dialysis facilities in the community. Liberty sees a need for both. However, Liberty has identified significant issues involving barriers to safe and convenient care, disruption of the lives of, and costs to nursing home residents that this proposed model will address. We urge the SHCC to approve Liberty's Petition for the demonstration project we have requested.

Exhibit C

Acute Care Services Committee
Agency Report
Adjusted Need Petition for an End-Stage Renal Disease Facility at a Skilled Nursing Facility as a Pilot Demonstration Project in the 2023 State Medical Facilities Plan

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Petitioner:
Liberty Healthcare & Rehabilitation Services

Contact:
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Request:
Liberty (Liberty) Healthcare & Rehabilitation Services requests a nursing home pilot demonstration project of six outpatient dialysis stations in Mecklenburg County to be located at Royal Park (Royal Park) of Matthews Rehabilitation and Health Center.

Background Information:
Chapter Two of the State Medical Facilities Plan (SMFP or the "Plan") provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allows for submission of petitions requesting adjustments to need projections to the State Health Coordinating Council (SHCC) in the summer. Any person may submit a certificate of need (CON) application for a need determination in the Plan. The CON review could be competitive and there is no guarantee that the petitioner would be the approved applicant.

There are two methodologies in the SMFP for End-Stage Renal Disease (ESRD) services: the county need methodology projects need for the county; the facility need methodology projects need for a specific facility. When a county need determination exists, an existing provider may apply to add stations in an existing facility. Anyone may apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations. The Petitioner is seeking a special need determination that falls outside both standard methodologies.

Outpatient (in-center) dialysis services in nursing homes have never been provided in North Carolina. In March 2022, the Petitioner requested Policy ESRD-4 be added to the 2023 SMFP. The Policy would have allowed for the development or expansion of a kidney disease treatment center at a skilled nursing facility. The Agency recommended denial of the petition because the summer petition process is available to propose an adjusted county need determination for this purpose. The Acute Care Services Committee and the SHCC voted to accept the Agency's recommendation and deny the Petition. The Agency also noted that the county need determination could stipulate that the new stations would have to be sited at a nursing home facility or "proximate to the nursing home building."

Analysis/Implications:

The Petition states that the development of an outpatient dialysis facility at a nursing home helps meet the Basic Principles outlined in the SMFP. Specifically, a facility would make dialysis services more accessible to patients and encourage home dialysis. It would also provide dialysis services at times that do not interfere with the patient's scheduled treatments, therapies/rehab, meals, medication, and family visits.

The use of demonstration projects in the SMFP are reserved to test the delivery and viability of unique approaches to health services having a statewide impact. The request to establish a new dialysis outpatient facility in a single county does not meet the requirements of a demonstration project.

Comments in response to the Petition discussed the proximity of dialysis facilities to Royal Park, suggesting that the patients have ample dialysis options nearby. The Petition makes the point that having a dialysis facility at a nursing home would alleviate the burden of transporting nursing home dialysis patients to existing dialysis facilities. Commenters also noted that because Mecklenburg County has 22 existing certified outpatient dialysis facilities and one proposed facility for a total of 579 stations (in the 2023 Proposed SMFP), the addition of six outpatient dialysis stations would create an unnecessary duplication of dialysis services in the county. It is doubtful that the addition of six stations at a nursing home facility would have an appreciable impact on dialysis providers in Mecklenburg County.

Additional comments expressed doubts that a nursing home facility could manage and provide quality dialysis in the same manner as an outpatient dialysis facility. It appears that the commenters assume that "regular" nursing home staff would be providing dialysis services. Conversely, as noted in the Agency Report presented at the April 12, 2022, Acute Care Services Committee meeting, the Centers for Medicare & Medicaid Services (CMS) established specific requirements for the provision of dialysis to nursing homes patients in the community and in nursing home facilities. The *CMS State Operations Manual*[1] (CMS SOM) (attached) specifically states that in-center dialysis may be provided by: transporting the resident to and from a separately certified ESRD facility located off-site of the nursing home; or transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or

[1] CMS State Operations Manual. (Rev. 205, 3-11-22). Chapter 2: The Certification Process, section 2271A – Dialysis in Nursing Homes, pp. 275-281. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf. Accessed August 22, 2022.

"proximate to the nursing home building." These dialysis treatments must be administered and supervised by personnel who meet the criteria for training and competency verification set forth in 42 CFR 494.100(a) and (b). In addition, dialysis services must be provided through a written agreement between the nursing home and the ESRD facility. In addition, home dialysis may be provided in nursing homes. Further, the CMS SOM outlines the requirements and provides guidance for mitigating risk for residents receiving dialysis treatment in a nursing home facility. In short, a dialysis facility at a nursing home must meet all the same qualifications and certification requirements as a dialysis facility in the community.

Agency Recommendation:

The Agency recognizes that dialysis patients in nursing homes are typically fragile. As such, it is reasonable that dialysis should be provided in a manner that is most appropriate to their healthcare needs. Proving dialysis in the nursing home facility is a viable option to achieve this goal. The SHCC has echoed these notions in previous discussions.

The Petition requested a "pilot demonstration" project. Demonstration projects in the SMFP test the delivery and viability of unique approaches to health services. Dialysis is provided successfully in nursing homes in quite a few states. Therefore, neither a formal pilot study nor a demonstration project is needed.

The Agency supports the standard methodologies for ESRD facilities. Based on these standard methodologies, the Agency cannot recommend a pilot demonstration project.

As an alternative, the Agency recommends approving a county need determination for six outpatient dialysis stations at a nursing home facility in Mecklenburg County with the following stipulations:

1) a licensed nursing home facility shall propose to develop at least the minimum number of stations required for Medicare certification by CMS as a dialysis facility; and
2) the new stations must be sited within a nursing home facility or "proximate to the nursing home building," i.e., on the same property as the nursing home facility; and
3) the dialysis facility must comply with the federal life safety and building code requirements applicable to a nursing home if located within it and the life safety and building code requirements appliable to dialysis facilities if located within the nursing home or "proximate to the nursing home building;" and
4) the Certificate of Need will include a condition requiring the dialysis facility to document that it has applied for Medicare certification no later than three years from the effective date of the CON; and
5) dialysis stations developed pursuant to this need determination are excluded from the planning inventory in the SMFP and excluded from the county and facility need methodologies; and
6) outpatient dialysis facilities developed pursuant to this need determination shall report utilization to the Agency in the same manner as other outpatient dialysis facilities.

As stated above, any person may submit a CON application for this need determination.

Excerpt from

State Operations Manual
Chapter 2 - The Certification Process

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(Rev. 205, 03-11-22)

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf

space/dimension and other requirements for each in-center dialysis stations and the home dialysis training and support room/area.

Home Training and Support Program:
Approval to provide home training and support services requires the dialysis facility to provide both home training to the patient and/or their care partner in the modality and ongoing support and monitoring of the patient/care partner, as outlined in 42 CFR §494.100. An approved home training and support program must include both training and support services. A dialysis facility that is approved to provide services to home patients must ensure through its interdisciplinary team that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable ESRD CfCs.

There are no requirements for a specification of the number of training stations. The expectation for these services is that there will be sufficient space to provide an appropriate learning environment for each patient and care partner, if applicable. The in-facility home dialysis training and support space must be large enough to accommodate the dialysis equipment, routine and emergency care, to afford patient privacy, and to prevent cross-contamination with pathogens.

In accordance with §494.100(c)(1)(vii), facilities which provide only home dialysis training and support must have a plan/arrangement in place to provide emergency back-up dialysis services when there is an interruption, or anticipated interruption, in a patient's routine home dialysis treatment. Situations that may require back-up dialysis services include, but are not limited to, non-functional equipment, power or water outages, availability of a designated care partner and/or a patient's anticipated travel away from their home.

The home dialysis support services may be provided directly by the ESRD facility or by arrangement with another ESRD facility. If the support services are provided by another ESRD facility, such arrangements should be made at a location as convenient to the patient's home as possible, regardless of facility ownership.

2271A - Dialysis in Nursing Homes

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Terms Used in This Guidance
The term "nursing home" in this guidance refers to a Skilled Nursing Facility (SNF) or a Nursing Facility (NF). The term "ESRD facility" refers to the certified end-stage renal disease (ESRD) facility that retains overall responsibility for all the dialysis care and services of the patient.

Overview: Dialysis for Nursing Home Residents
Medicare reimbursement for dialysis services is available to certified ESRD facilities. All dialysis patients must be under the care of a certified ESRD facility to have their outpatient dialysis care and treatments reimbursed by Medicare.
Nursing homes are not required to accommodate dialysis services on-site. Some State regulations may not allow dialysis services to be provided in a nursing home setting, or

may have additional requirements regarding the qualifications of personnel who provide dialysis treatments in a nursing home.

Residents of a nursing home may receive chronic dialysis treatments through two options:

1. **In-Center Dialysis:**
   - Transporting the resident to and from a separately certified ESRD facility that is located off-site of the nursing home for dialysis treatments; or
   - Transporting the resident to and from a separately certified ESRD facility providing in-center dialysis located within the nursing home or proximate to the nursing home building.

2. **Home Dialysis in a Nursing Home**:
   Residents may receive dialysis treatments in the nursing home. These dialysis treatments are administered and supervised by personnel who meet the criteria for training, and competency verification in 42 CFR 494.100(a) and (b) as also stated in this guidance, and are provided through a written agreement between the nursing home and the ESRD facility.

Mitigating risks for residents receiving dialysis treatments in a nursing home include: 1) ensuring only qualified personnel administer, monitor, and supervise the dialysis treatments; 2) monitoring the dialysis patient's status before, during, and after the treatments; and 3) ensuring a safe and sanitary environment for the treatments.

The goal of this guidance is to ensure that an ESRD facility, providing home dialysis services to a nursing home resident under a written agreement with the resident's nursing home, maintains direct responsibility for the dialysis related care and services provided to the nursing home resident(s) consistent with the ESRD Conditions for Coverage (CfC) requirements as well as the terms of an applicable agreement with the nursing home.

ESRD Notification to the State Survey Agency of a New or Additional Contract with a Nursing Home to Provide Dialysis Services On-Site

No additional approval is required from CMS for an ESRD facility to enter into an agreement with a nursing home to provide dialysis services to nursing home residents. However, the ESRD facility must notify its State Survey Agency (SA) of any such agreement(s). This notification is accomplished through submitting a completed Form CMS-3427 End Stage Renal Disease Application and Survey and Certification Report. Only the following applicable fields of the Form CMS-3427 must be completed for this notification:

- Field: (1) #6 Other
- Field: (2) Name of Dialysis Facility
- Field: (3) CCN
- Field: (4) Street Address of Dialysis Facility
- Field: (6) City
- Field: (7) County
- Field: (9) State
- Field: (10) Zip Code
- Field: (12) Telephone Number
- Field: (22) Dialysis in LTC Facility Field:
- Field: (26) How is isolation provided in the nursing home?

Written Agreement between the ESRD Facility and the Long Term Care Facility

The ESRD facility is expected to enter into a written agreement with any individual nursing home for which they will provide dialysis services. The agreement delineates the responsibilities of the ESRD facility and the nursing home regarding the care of the resident before, during, and after dialysis treatments.

The ESRD facility is ultimately responsible for the safe delivery of dialysis to the nursing home resident which would include review of the qualifications, training, competency verification, and monitoring of all personnel who administer dialysis treatments in the nursing home and who provide on-site supervision of dialysis treatments. The ESRD facility is responsible for the quality and safety of the dialysis treatments and the management of the residents' ESRD-related conditions. The ESRD facility is also responsible for providing all equipment necessary for the resident's dialysis treatment and for the maintenance of such equipment.

The nursing home is responsible for providing a safe environment for the dialysis treatments, monitoring the resident before, during, and after dialysis treatments for complications possibly related to dialysis, and provides all non-dialysis related care. Nursing home staff must be prepared to appropriately address and respond to dialysis related complications and provide emergency interventions, as needed. See 42 CFR §483.25(l) and SOM App. PP at tag F698.

Both the ESRD facility and the nursing home are responsible for ensuring the collaboration necessary to provide dialysis care coordination to each nursing home resident receiving dialysis treatments.

The written agreement must be signed by authorized representatives of the Medicare-certified dialysis facility and the nursing home prior to the provision of dialysis care at the nursing home and must:

1. Delineate the lines of authority of each party;
2. Delineate the responsibilities of each party;
3. Describe how coordination between the parties will occur;
4. Describes the accountability for the dialysis services provided;
5. Be consistent with the written policies and procedures of the ESRD facility and the nursing home;
6. Specify the method by which the parties will ensure adherence to the terms of the agreement, communicate as issues arise, and take remedial action when appropriate; and
7. Be reviewed at least annually, and updated as needed.

ESRD Policies and Procedures for Services to Residents Located in a Nursing Home

At a minimum, the ESRD facility, in collaboration with the nursing home, must develop and implement protocols for the delivery of ESRD services that are equivalent to the standards of care provided to dialysis patients receiving treatments in a dialysis facility. The protocols must include requirements set forth at 42 CFR 494.30 and 494.80 through 494.100. These protocols include procedures for infection control, patient assessment, patient plans of care, and care of the dialysis patient at home.

Policies and procedures must be reviewed and updated as necessary to be consistent with the most current standards of practice. Timeframes for re-evaluation of policies and procedures should be determined by each ESRD facility.

Dialysis Supervision and Administration

The ESRD facility providing services to a resident in a nursing home must ensure:

1. Onsite supervision of dialysis by a trained registered nurse (RN) (who has completed a training course approved by the ESRD facility) whenever a resident is receiving hemodialysis (HD) in the nursing home, and by a trained RN or licensed practical/vocational nurse (LPN/LVN) (who has completed a training course approved by the ESRD facility) when a resident is receiving peritoneal dialysis (PD) treatment in the nursing home;
2. Qualified/trained dialysis administering personnel are present in the room and maintain direct visual contact with the resident receiving HD throughout the entire duration of the treatment (the supervising nurse may also be the dialysis administering personnel); and
3. If a situation occurs where the nursing home is unable to provide dialysis treatments due to reasons such as insufficient trained staff and/or supervision, the ESRD facility is notified and provides the dialysis treatments to avoid a delay or cancellation of treatment.

Documentation of training and competency verifications for nursing home staff should be maintained by both the ESRD and nursing home facility.

Hemodialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a trained supervising RN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's hemodialysis treatment. The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs who supervise hemodialysis treatments in the nursing home must have successfully completed a training program which:

- Covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii);
- Is approved by the dialysis facility medical director and governing body;
- Is administered under the direction of a home training nurse meeting the qualifications at §494.140(b)(2); and
- Is equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100(b)(1).

Peritoneal Dialysis Treatment Supervision: Qualifications and Training

The ESRD facility must ensure that a qualified supervising RN/LPN/LVN is constantly present on-site at the nursing home and immediately available to respond to concerns or emergencies that may occur during a resident's PD treatment (i.e. automated PD, continuous ambulatory PD). The supervising nurse must be present in the general area where the resident(s) are receiving dialysis and be readily available. If the supervising nurse has other nursing duties in the nursing home, these other duties must not hinder or negatively affect his/her ability to respond immediately to the needs of the dialysis patient(s).

Training: RNs/LPNs/LVNs who supervise PD treatments in the nursing home must successfully complete a training program that is:

- Specific to PD care and covers, at a minimum, the subjects listed at §494.100 (a)(3)(i)-(viii)
- Approved by the dialysis facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i)-(viii) and §494.100 (b)(1).

Hemodialysis and Peritoneal Dialysis Administration

Qualifications: The personnel who initiate and discontinue dialysis treatments for HD and PD to nursing home residents must be a RN, LPN or LVN who meets the practice requirements in the State in which he or she is employed. A trained nursing home staff member such as a nurse aide or trained caregiver may monitor the patient for the duration of the patient's treatment, but initiation and discontinuation of HD and PD must only be performed by the supervising nurse.

Training: The dialysis administering personnel, for example RN, LPN/LVN, nurse aide or trained caregiver, must receive adequate training and possess sufficient competency to ensure that the resident on dialysis receives a safe and effective treatment. The training must be:

- Equivalent to the ESRD facility training and competency verification for home dialysis patients at §494.100 (a)(3)(i-viii) and §494.100 (b)(1).
- Approved by the ESRD facility medical director and governing body;
- Administered under the direction of a home dialysis training nurse meeting the qualifications at §494.140(b)(2) and;
- Specific to the dialysis modality. The training program for HD and PD must include at least the subject matter listed at §494.100 (a)(3)(i-viii) .

Ongoing competency for dialysis administering personnel must be verified through visual audits by an ESRD RN who meets the qualifications of home training nurse at §494.140(b)(2) . Frequency for competency verification is determined by the ESRD facility. More frequent competency checks may be warranted if problems in care are identified. For example, a concern of poor clinical outcomes, such as frequent infections, may indicate infection control issues and may be an indicator to review dialysis procedures performed by the nursing home staff and possible re-training.

In-Room Presence

To assure resident safety, the ESRD facility and nursing home must ensure that qualified dialysis administering personnel remain in the room with direct visual contact of the resident and their vascular access throughout the hemodialysis treatment, in accordance with §494.60(c)(4).

Existing Personal Caregiver

If an existing ESRD facility home dialysis (PD or home HD) patient is admitted to a nursing home and that patient has a trained personal caregiver who administered the dialysis treatments at home, that caregiver may be approved by the ESRD facility and the

nursing home to continue to administer the patient's dialysis treatments in the nursing home. The collaborative decision-making process for such situations must be addressed in the written agreement between the ESRD facility and nursing home. If the nursing home and ESRD facility determine that an existing home dialysis caregiver may continue to administer the dialysis in the nursing home, the ESRD facility must assure that the caregiver meets the training requirements at §494.100(a)(3)(i-viii), and the verification of demonstrated competency at §494.100(b)(1). The ESRD facility is responsible for the ongoing monitoring of the competency of the personal caregiver.

Coordination of Care

Communication

The ESRD facility and nursing home must establish procedures for 24/7 communication between the two entities. The ESRD facility must provide to the nursing home an on-call schedule with the names and contact information of physicians and/or ESRD facility RN's to be called for emergencies. There should be written agreement on a communication process to include how communication and responses will be coordinated and documented between the ESRD facility and nursing home staff.

Interdisciplinary Team (IDT) Coordination between ESRD Facility and Nursing Home Staff

The dialysis facility IDT team must coordinate with the nursing home staff for the development and implementation of an individualized care plan based on the patient's assessment. Both the nursing home staff and ESRD facility staff are responsible for monitoring and addressing any medical or non-medical needs that are identified. Any identified barriers or issues that are preventing residents from meeting the established ESRD facility goals identified through a patient assessment and/or defined in the plan of care, should be promptly communicated between the ESRD facility IDT and the nursing home IDT. Any barriers experienced by a dialysis patient will require re-assessment and an updated plan of care by both teams.

Emergency Plans

The dialysis facility maintains overall responsibility to prepare the nursing home to address all emergencies related to the dialysis needs of the resident receiving treatments in the nursing home. The following emergency plans must be clear and communicated to nursing home staff in a manner that allows for the continuity of care and be incorporated into the written agreement between the two entities:

1. **Emergency Staffing**
   When the nursing home staff are functioning as the caregiver for the nursing home resident and providing the dialysis treatment for the resident, it is the responsibility of the nursing home staff to notify the ESRD facility of any delays or interruptions in the provision of the prescribed dialysis treatment. The ESRD facility is responsible for ensuring that a backup plan is in place to ensure the resident receives the treatment.
2. **Emergency Care**
   Nursing Home residents receiving dialysis may have complications which require treatment with emergency medications or equipment. The physician treatment orders for the ESRD patient should include what emergency medications are to be kept on hand.
3. **Equipment Failure**
   The ESRD facility must provide nursing home staff with:

- Adequate and appropriate education for possible equipment failures and risk(s) associated with equipment failures;
- Troubleshooting techniques; and
- Contact information for assistance in resolving issues with equipment failure.

Any equipment that is non-functional must be replaced or restored by the ESRD facility to avoid interruption of a patient's dialysis treatment.

4. **Emergency Supplies**
   Nursing homes should maintain all necessary medication and supply inventories to prevent any delays or interruptions to a resident's prescribed dialysis treatment. The ESRD facility and the nursing home should ensure a reserve of supplies to be available in emergency circumstances. The emergency supply reserve is in excess of the routine supply inventory and generally includes at least five (5) days of emergency supplies for each resident.
   To assist with the inventory, the ESRD facility should provide nursing homes with medications, equipment, and dialysis related supplies through routine deliveries. Plans must be in place for the safe delivery of additional supplies in the event of an emergency.

2271B - Dialysis in Hospitals

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

A department/unit of a hospital (other than a psychiatric hospital) may, as permitted under State law, provide either inpatient or outpatient dialysis services.
In certain situations dialysis services may be provided in a hospital department/unit for non-ESRD patients requiring temporary dialysis or for ESRD patients who are admitted to the hospital for other diagnoses or injuries. These dialysis services are referred to as "acute dialysis." A department /unit of a hospital that provides acute dialysis services must provide those services in compliance with the hospital Conditions of Participation (CoP) and are not subject to the ESRD CfCs.
Hospitals that provide outpatient dialysis services must be certified as a hospital-based ESRD facility.

2272 - ESRD Facility Classification

(Rev. 181, Issued: 09-21-18, Effective: 09-21-18, Implementation: 09-21-18)

Hospital-Based ESRD Facility
A hospital-based ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and that meets the ESRD CfCs at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital or critical access hospital (CAH) and is physically located on the hospital campus. If a hospital operates multiple separately certified hospital-based ESRD facilities, each separate ESRD facility must have its own CMS certification number (CCN).
A hospital-based ESRD facility is discussed at 42 CFR §413.174(c) and meets the following criteria:

- The ESRD facility and hospital have a common governing body and are subject to