TOPCATS Division
2321 West Morehead Street
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August 9, 2023

Dr. Andrea Emanuel, Interim Assistant Chief, Healthcare Planning
Dr. Sandra B. Greene, Chair, Acute Care Services Committee
Ms. Elizabeth Brown, Planner, Acute Care Services Committee
Healthcare Planning Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Re: DaVita's Comments Opposing Liberty Healthcare and Rehabilitation Services' 24 Petitions for Adjusted Facility Need Determination for Outpatient Dialysis Stations at a Nursing Home Facility in 24 NC Counties the 2024 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

DaVita Kidney Care ("DaVita") offers the following comments opposing Liberty Healthcare and Rehabilitation Services' ("Liberty's") 24 Petitions for Adjusted Facility Need Determination for Outpatient Dialysis Stations at a Nursing Home Facility in 24 NC Counties ("Liberty's 24 Summer Petitions") in the 2024 State Medical Facilities Plan ("SMFP").

Liberty Petitions for Adjusted Need Determinations for Outpatient Dialysis Stations at a Nursing Home Facility

	Service Area (County)	# of Stations Requested
1	Alamance	13
2	Bertie	4
3	Brunswick	6
4	Buncombe	16
5	Chatham	4
6	Columbus	4
7	Cumberland	28
8	Davie	4
9	Durham	34
10	Forsyth	38
11	Franklin	8
12	Halifax	11
13	Johnston	14
14	Lee	8
15	Mecklenburg	59
16	Moore	7
17	New Hanover	17
18	Orange	7
19	Person	6
20	Robeson	7
21	Rowan	7
22	Sampson	6
23	Wake	57
24	Watauga	4
	TOTAL	369

In support of its Summer 2023 Petition, Liberty relies on many of the same arguments it advanced in its Spring 2022 Petition, Summer 2022 Petition, and Spring 2023 Petitions ("Previous Liberty Petitions"), each of which DaVita addressed in the comments ("Previous DaVita Comments") it filed with the Acute Care Services Committee (the "Committee"). Consequently, DaVita restates herein many of the same criticisms it previously lodged against Previous Liberty Petitions. Attached at Exhibit 1 are DaVita's Comments on Liberty's Spring 2023 Petition to provide greater detail on DaVita's specific concerns regarding how Liberty ignores the clinical realities inherent in providing dialysis services.

In short summary, the Committee and the SHCC should deny Liberty's 24 Summer Petitions for the following additional reasons:

1. Although Liberty's 24 Summer Petitions include quantitative data, the novel methodology presented in the petitions is based on faulty assumptions and discordant data analysis which fail to justify an adjusted, special need determination for any of the counties in Liberty's 24 Summer Petitions.

2. The addition of any and all of the need determinations proposed in Liberty's 24 Summer Petitions would undermine the state health planning process and unnecessarily duplicate dialysis services statewide.

Introduction

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

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

I. Liberty's 24 Summer Petitions Fail To Satisfy The SMFP's Special Needs Petition Requirements.

Each of Liberty's 24 Summer Petitions begin with the claim that the "Petition is consistent with the description and definition of Summer Petitions contained at pages 8-9 of the 2023 SMFP."

However, that is not the case. In the Statement of Requested Change, Liberty's 24 Summer Petitions request both:

1. the addition of a ***county need determination*** for outpatient dialysis stations at a nursing home facility; and
2. "a change only to the 2024 draft ***need methodology*** for [Petition's] County"

Setting aside that pursuant to Chapter 2 of the 2023 SMFP, petitions for changes to need determination methodologies are to be submitted in the Spring, the latter request is, by definition, a change to the SMFP that has the potential for *statewide effect*. Liberty frames its request as though it believes that there could be 100 different need methodologies that could be applied to each of the state's counties. The committee should reject this framing as it does not align with the ESRD planning process or the standard methodologies.

Pursuant to the special needs petition mechanism, "Petitioners may submit a written petition requesting an adjustment to the need determination in the Proposed SMFP if they believe that **special attributes of a service area or institution** give rise to resource requirements that differ from those provided by the standard methodologies and policies."[1] Although facility-specific data is applied to the methodology developed in Liberty's 24 Summer Petitions, Liberty does not identify any service area-specific or facility-specific attributes that warrant departure from the standard need methodologies. Liberty relies on its made-up methodology, not the data, to justify the requested need determinations.

The methodology that Liberty has concocted appears to be a conflation of the two ESRD standard methodologies. Further, the quantitative data underpinning the need determinations calculated in Liberty's 24 Summer Petitions are based on facility level data and use of this data has the effect of overstating the percentage of nursing home patients used in Liberty's methodology making this novel methodology defective. It is also notable that while 22 of Liberty's 24 Summer Petitions are for need adjustments in NC counties where Liberty provides skilled nursing and short-term rehabilitation services[2], none of these petitions provide any insight into any data regarding the ESRD patients served by Liberty.

Liberty's 24 Summer Petitions fail to show the Committee any special circumstances that merit departure from the SMFP's standard methodology and Basic Principles, which are designed to ensure that dialysis providers in North Carolina operate in a cost-effective manner and provide quality care.

II. Approval of Liberty's 24 Summer Petitions Would Undermine the State Health Planning Process and Unnecessarily Duplicate Dialysis Services Statewide.

Liberty's 24 Summer Petitions advocate a radical departure from the SMFP methodologies for dialysis services, which will both undermine the state health planning process and result in the

[1] 2023 SMFP, p. 8 (emphasis supplied).

[2] *See* https://libertyhealthcareandrehab.com/find-a-facility/ (last accessed August 1, 2023).

unnecessary duplication of services statewide. In addition to the clinical considerations discussed in DaVita's Previous Comments (see Exhibit 1), this is a standalone reason why the Committee and SHCC should decline to adopt the adjusted need determinations in Liberty's 24 Summer Petitions.

A. State Health Planning Process

DaVita believes that it is advisable to monitor the results of the adjusted need determination for Mecklenburg County -- included in the 2023 SMFP as a direct result of Liberty's advocacy in last year's health planning cycle -- before considering the policy of statewide effect Liberty proposes. As the Committee will recall, Liberty first advocated for proposed Policy ESRD-4 in its Spring 2022 Petition. The Committee rejected this effort, believing the sounder approach to be Liberty utilizing the summer special needs petition process. Liberty availed itself of this process, seeking an adjusted need for a demonstration project which Liberty, and only Liberty, would be able to develop in Mecklenburg County. The SHCC rejected this petition as well, but nevertheless recommended an adjusted need determination for nursing home-sited ESRD facility stations in Mecklenburg County on its own initiative.

In essence, the Committee (and the SHCC, which adopted the Committee's recommendation), approved a "pilot" adjusted need determination to vet the viability of a nursing home-based dialysis facility. Throughout this planning year, committee members have expressed concern for creating unintended consequences as a result of any SHCC-approved changes to ESRD policy developed in an effort to address the concerns raised by Liberty in its previously denied petitions. It would be premature to approve the inclusion of need determinations for up to 369 additional dialysis stations before knowing who applies for the adjusted need determination in the 2023 SMFP, the progress of that project's development, and the viability of such a project. Nursing home-based dialysis facilities are a brand new concept in North Carolina, and the Committee and SHCC should not rush to approve additional need determinations before assessing their feasibility. Approving Liberty's 24 Summer Petitions before doing so would undermine the purpose of the state health planning process, and defeat the purpose of the Mecklenburg County adjusted need determination's inclusion in the 2023 SMFP.

Further, DaVita notes that the Mecklenburg County adjusted need determination, which Liberty's 24 Summer Petitions are modeled after, was an Agency-recommended alternative to Liberty's 2022 Summer Petition received and adopted at a point in the 2023 planning process where there was no opportunity for the Committee to formally receive comments from the public. If the Committee is inclined to adopt any of Liberty's 24 Summer Petitions, or consider Agency recommendations offered in the alternative, it should impose additional stipulations that align with Liberty's intention behind the proposal -- avoiding nursing home resident travel -- and the SHCC's Policy ESRD-3 framework. Specifically, DaVita recommends adding the following two conditions / stipulations:

- The nursing home must own the outpatient dialysis facility, but the nursing home may contract with another legal entity to operate the facility.

- The nursing home must document that the patients it proposes to serve in an outpatient dialysis facility within the nursing home facility or "proximate to the nursing home building" pursuant to this adjusted need determination are residents of the applying nursing home.

These proposed additions reflect prior Agency-guided and SHCC-approved policy-making considerations, specifically as they relate to ESRD planning. Moreover, they explicitly address Liberty's assertion that, in these current and all its previously denied petitions, that the proposals are not intended to replace outpatient dialysis facilities in the community. Although the spirit and intent of the proposed Dialysis Need Determination is to permit nursing homes to apply to serve a very specific and unique subset of patients -- nursing home residents at the applying facility -- the conditions proposed in Liberty's 24 Summer Petitions do not ensure that applying nursing homes comply with that intent. That can be remedied by our additional proposed conditions above. Attached at Exhibit 2 are the comments DaVita submitted to the SHCC Chairperson last summer.

B. Unnecessary Duplication of Services Statewide

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

According to its website, Liberty operates 39 nursing homes in 25 North Carolina counties. Twenty-four of these 25 counties contain existing dialysis facilities. While it omitted any statistics regarding its nursing home patients who require dialysis from its 2023 Spring Petition, Liberty's 2022 Spring Petition stated that "twenty-seven (27) of [its] nursing home facilities have at least one dialysis resident, serving 80 total dialysis nursing home residents." It is likely that each of those residents is already treating in one of these existing dialysis facilities. The same can be said of such patients at every other nursing home in the state. Liberty's 24 Summer Petitions propose need determinations totaling an additional 369 dialysis stations based on a novel methodology which essentially double-counts patients that are already included in the ESRD standard methodologies. When looking on a county-by-county basis, Liberty's 24 Summer Petitions seek to increase each county's station count by an average of almost 15%. In some cases, the stations available would increase by 20%. It is clear that Liberty's 24 Summer Petitions would unnecessarily duplicate services that are already being provided to patients in these counties.

III. Conclusion

For the foregoing reasons, DaVita respectfully requests that the Committee and the SHCC reject Liberty's 24 Summer Petitions and refrain from inserting any adjusted need determination for outpatient dialysis stations at a nursing home facility in the 2024 SMFP.

Sincerely,

Esther N. Fleming
Director, Healthcare Planning

Exhibits

1. DaVita's Comments on Liberty's Spring 2023 Petition

2. September 26, 2022 Comments on the Agency's Recommended Alternative to Liberty's Summer 2022 Petition

3. Map of Liberty's Locations in North and South Carolina, https://libertyhealthcareandrehab.com/find-a-facility/

Exhibit 1

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March 15, 2023

Dr. Andrea Emanuel, Interim Assistant Planning Chief, Healthcare Planning
Mr. John E. Young, Chair, Acute Care Services Committee
Dr. Charul G. Haugan, Vice-Chair, Acute Care Services Committee
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809 Ruggles Drive
Raleigh, NC 27603

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

Dear Acute Care Services Committee Members:

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

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

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

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

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

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

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

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

[3] 42 C.F.R. § 494.140.

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

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

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

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

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

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

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

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

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

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

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

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

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

A. State Health Planning Process

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

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

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

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

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

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

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

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

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

B. Unnecessary Duplication of Services Statewide

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[13] *Id.*

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

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

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

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

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

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

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

[15] *Id.*

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

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

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

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

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

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

[17] 42 C.F.R. § 494.20.

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

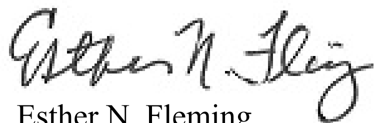
[19] 2023 SMFP, p. 22 (emphasis supplied).

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

VI. Conclusion

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

Sincerely,



Esther N. Fleming
Director, Healthcare Planning

Exhibit 2

TOPCATS Division
2321 West Morehead Street
Charlotte, NC 28208

September 26, 2022

Dr. Sandra B. Greene, Chair, State Health Coordinating Council
Dr. Amy Craddock, Assistant Chief, Healthcare Planning
Ms. Elizabeth Brown, Planner, Acute Care Services Committee
Healthcare Planning Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, NC 27603

Re: DaVita's Comments Regarding the Agency's Recommendation for an Adjusted County Need Determination for Six Outpatient Dialysis Stations at a Nursing Home Facility in Mecklenburg County in the 2023 State Medical Facilities Plan

Dear Dr. Greene and State Health Coordinating Council Members:

At its September 13 meeting, the Acute Care Service Committee ("ACSC") denied Liberty's Petition for an Adjusted Facility Need Determination for Nursing Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 SMFP ("Liberty's Petition"). However, the ACSC received and adopted an Agency-recommended alternative to Liberty's request, a special county need determination with six conditions, enclosed at Exhibit 1 (the "proposed Dialysis Need Determination").

DaVita Kidney Care ("DaVita") offered comments on Liberty's Petition, but had no formal opportunity to comment on this new proposed Dialysis Need Determination. Thus, DaVita offers the following comments to the State Health Coordinating Council (SHCC).

If the SHCC approves the proposed Dialysis Need Determination, its conditions should align with Liberty's intention behind the proposal (avoiding nursing home resident travel) and the SHCC's Policy ESRD-3 framework. **Specifically, DaVita recommends adding the following two conditions / stipulations:**

> 7) The nursing home must own the outpatient dialysis facility, but the nursing home may contract with another legal entity to operate the facility.
>
> 8) The nursing home must document that the patients it proposes to serve in an outpatient dialysis facility within the nursing home facility or "proximate to the nursing home building" pursuant to this adjusted need determination are residents of the applying nursing home.

These proposed additions reflect prior Agency-guided and SHCC-approved policy-making considerations, specifically as they relate to ESRD planning. Although the spirit and intent of the proposed Dialysis Need Determination is to permit nursing homes to apply to serve a very specific and unique subset of patients -- nursing home residents at the applying facility -- the currently proposed conditions do not ensure that applying nursing homes comply with that intent. That can be remedied by our additional proposed conditions above.

In response to questions from ACSC members, the staff indicated that the process that led them to include certain stipulations in the proposed Dialysis Need Determination was comparable to the process that led to elements of Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus. Policy ESRD-3 was created "to enable any hospital to offer outpatient dialysis services to patients who are not appropriate for community-based facilities but are also not inpatients,"[1] beginning in the 2021 SMFP. In both cases, the petitioners, UNC Hospitals in 2019 and Liberty in 2022, assured that their proposals were not intended to replace outpatient dialysis facilities in the community because both wanted to serve a very specific population of dialysis patients.

This point was explicitly acknowledged and addressed in the Agency Request regarding Policy ESRD-3 which states, "[i]t is not the Agency's intent to use the proposed policy to supplant outpatient dialysis facilities in the community."[2] The following are among the conditions Policy ESRD-3 requires of applicants:

> *2. The hospital must own the outpatient dialysis facility, but the hospital may contract with another legal entity to operate the facility.*
>
> *3. The 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.*[3]

While the proposed Dialysis Need Determination opens the door for nursing homes to become dialysis providers, it does not presently reflect the same focus as Policy ESRD-3. That is, it does not require applicants to show that they are addressing the specific concern presented by the petitioner and supported by the Agency and the ACSC -- meeting a specific need for <u>dialysis patients who reside in the applying nursing home</u>. DaVita's two proposed additional conditions above assure that focus.

Sincerely,

Esther N. Fleming
Director, Healthcare Planning

[1] Acute Care Services Committee, Agency Request, Policy ESRD-3: Development of Outpatient, Dialysis Facilities on a Hospital Campus, April 7, 2020, page 1 (Exhibit 2).
[2] Acute Care Services Committee, Agency Request, Policy ESRD-3: Development of Outpatient, Dialysis Facilities on a Hospital Campus, April 7, 2020, page 1 (Exhibit 2).
[3] North Carolina 2022 State Medical Facilities Plan, page 22.

Exhibits

1. 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

2. Acute Care Services Committee, Agency Request, Policy ESRD-3: Development of Outpatient, Dialysis Facilities on a Hospital Campus, April 7, 2020

Exhibit 1

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:
David Holmes
Vice President of Business Development
2334 S. 41st Street
Wilmington, NC 28403
910-815-3122
dholmes@libertyhcare.com

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

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[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

Table of Contents
(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

Exhibit 2

Acute Care Services Committee
Agency Request
Policy ESRD-3: Development of Outpatient Dialysis Facilities on a Hospital Campus
April 7, 2020

Healthcare Planning (HP) proposes Policy ESRD-3 to allow hospitals to develop a kidney disease treatment center ("outpatient dialysis facility") on a hospital campus without the requirement of a need determination. Last year the Agency received a petition from UNC Hospitals to develop an outpatient dialysis facility on a hospital campus. Discussions with the committee and within the Agency favored creation of a policy to enable any hospital to offer outpatient dialysis services to patients who are not appropriate for community-based facilities but are also not inpatients. It is not the Agency's intent to use the proposed policy to supplant outpatient dialysis facilities in the community.

As of 2018, about 40% of hospitals had inpatient dialysis stations (2019 Hospital License Renewal Applications). When hospitals provide dialysis treatments to outpatients, they cannot receive reimbursement via the inpatient dialysis program. Eligibility for reimbursement requires the hospital to have a Medicare-certified outpatient dialysis facility. Under normal circumstances, development of an outpatient dialysis facility at the hospital would require a county need determination. County need determinations are very rare, however.

The intent of the proposed policy is to enable hospitals to be reimbursed for providing outpatient dialysis to individuals that they need to serve at the hospital. To receive Medicare reimbursement for outpatient dialysis, the Centers for Medicare and Medicaid Services (CMS) requires that the hospital own the outpatient dialysis facility. The hospital does not have to operate the facility, however.

The Basic Principles in Chapter 9 require a new dialysis facility to have at least 10 stations to be cost-effective and assure quality of care. Given that hospitals are likely to have the necessary infrastructure to house outpatient dialysis stations, we propose to waive this requirement.

Finally, we propose to exclude existing and newly-developed outpatient dialysis facilities on a hospital campus from the county and facility need determination methodologies[1]. Such facilities are likely to have relatively low utilization because they will serve a specialized population. Therefore, we propose to exclude a facility's utilization from the county need methodology because the utilization is unlikely to achieve 80%; thus a county with a hospital-based outpatient dialysis facility would be very unlikely ever to have a county-based need for dialysis stations. Also, if a hospital-based outpatient facility needs to increase the number of stations, the proposed policy contains a mechanism to allow expansion.

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[1]Carolinas Medical Center (Levine Children's Hospital), NC Baptist Hospital, and Novant Presbyterian Medical Center have outpatient dialysis facilities.

Proposed Policy

Policy ESRD-3: Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus

Licensed acute care hospitals (see stipulations in G.S. 131E-77 (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 hospital proposes to develop or expand the facility on any campus on its license where general acute beds are located.

2. The hospital must own the outpatient dialysis facility, but the hospital may contract with another legal entity to operate the facility.

3. The 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.

4. The hospital must establish a relationship with a community-based outpatient dialysis facility to assist in the transition of patients from the hospital outpatient dialysis facility to a community-based facility wherever possible.

The hospital shall propose to develop at least the minimum number of stations allowed for Medicare certification by the Centers for Medicare and Medicaid Services (CMS). Certificate of need will impose a condition requiring the hospital 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 hospital pursuant to this policy.

Dialysis stations developed pursuant to this policy are excluded from the inventory in the SMFP and excluded from the facility and county need methodologies. Certified outpatient dialysis stations that existed in hospitals as of the date of implementation of this policy will be removed from the inventory and methodologies; these facilities will be treated as though the stations were developed pursuant to this policy.

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 3

Liberty Healthcare & Rehabilitation Services

Caring with Excellence

Providing Skilled Nursing and Short Term Rehabilitation Services In Locations Across North and South Carolina

2 States, 25 Counties, 39 Locations - All Proudly Caring With Excellence

NORTH CAROLINA

Alamance County
Liberty Commons Nursing & Rehabilitation Center of Alamance County
791 Boone Station Drive
Burlington, NC 27215
(336) 586-9850

Bertie County
• *Three Rivers Health & Rehabilitation Center*
1403 Conner Drive
Windsor, NC 27983
(252) 794-4441

Bladen County
• *Elizabethtown Healthcare & Rehabilitation Center*
208 Mercer Road
Elizabethtown, NC 28337
(910) 862-8181

Brunswick County
Southport Health & Rehabilitation Center
630 N Fodale Ave
Southport, NC 28461
(910) 457-9581

Buncombe County
• *Pisgah Manor*
104 Holcombe Cove Road
Candler, NC 28715
(828) 667-9851

Columbus County
Liberty Commons Nursing & Rehabilitation Center of Columbus County
1402 Pinckney Street
Whiteville, NC 28472
(910) 642-4245

• *Shoreland Health Care & Retirement Center*
200 Flowers-Pridgen Drive
Whiteville, NC 28472
(910) 642-4300

Cumberland County
• *Golden Years Nursing Home*
7348 North West Street
Falcon, NC 28342
(910) 980-1271

Highland House Rehabilitation & Healthcare
1700 Pamalee Drive
Fayetteville, NC 28301
(910) 488-2295

• *Woodlands Nursing & Rehabilitation Center*
400 Pelt Drive
Fayetteville, NC 28301
(910) 822-0515

Davie County
Bermuda Commons Nursing & Rehabilitation Center
316 NC Highway 801 South
Advance, NC 27006
(336) 998-0240

Forsyth County
• *Oak Forest Health & Rehabilitation Center*
5680 Windy Hill Drive
Winston-Salem, NC 27105
(336) 776-5000

The Oaks
901 Bethesda Road
Winston-Salem, NC 27103
(336) 768-2211

Summerstone Health & Rehabilitation Center
485 Veteran's Way
Kernersville, NC 27284
(336) 515-3000

Franklin County
• *Louisburg Healthcare & Rehabilitation Center*
202 Smoketree Way
Louisburg, NC 27549
(919) 496-2188

Louisburg Manor
114 Smoketree Way
Louisburg, NC 27549
(919) 496-6084

Halifax County
• *Liberty Commons Nursing & Rehabilitation Center of Halifax County*
101 Caroline Avenue
Weldon, NC 27890
(252) 536-4817

Johnson County
Liberty Commons Nursing & Rehabilitation Center of Johnston County
2315 Highway 242 North
Benson, NC 27504
(919) 207-1717

Lee County
Liberty Commons Nursing & Rehabilitation Center of Lee County
310 Commerce Drive
Sanford, NC 27332
(919) 499-2206

Westfield Rehabilitation and Health Center
3100 Tramway Road
Sanford, NC 27332
(919) 775-5404

Mecklenburg County
Briar Creek Health Center at The Barclay
6041 Piedmont Row Drive
Charlotte, NC 28208
(980) 443-6760

Royal Park Rehabilitation and Health Center
2700 Royal Commons Lane
Matthews, NC 28105
(704) 849-6990

• *The Pavilion Health Center at Brightmore*
10011 Providence Road West
Charlotte, NC 28277
(980) 245-8500

Moore County
• *Pinehurst Healthcare & Rehabilitation Center*
300 Blake Road
Pinehurst, NC 28374
(910) 295-6158

• *The Inn at Quail Haven Village*
155 Blake Road
Pinehurst, NC 28374
(910) 295-2294

New Hanover County
Bradley Creek Health Center at Carolina Bay
740 Diamond Shoals Road
Wilmington, NC 28403
(910) 769-7550

• *Liberty Commons Rehabilitation Center*
121 Racine Drive
Wilmington, NC 28403
(910) 452-4070

Orange County
Parkview Health & Rehabilitation Center
1716 Legion Road
Chapel Hill, NC 27517
(984) 234-3600

Person County
• *Roxboro Healthcare & Rehabilitation Center*
901 Ridge Road
Roxboro, NC 27573
(336) 599-0106

Rowan County
Liberty Commons Nursing & Rehabilitation Center of Rowan County
4412 South Main Street
Salisbury, NC 28147
(704) 637-3040

Sampson County
Mary Gran Nursing Center
120 Southwood Drive
Clinton, NC 28329
(910) 592-7981

• *Southwood Nursing & Rehabilitation Center*
180 Southwood Drive
Clinton, NC 28329
(910) 592-8165

Wake County
Capital Nursing & Rehabilitation Center
3000 Holston Lane
Raleigh, NC 27610
(919) 231-6045

• *Swift Creek Health Center at The Templeton*
221 Brightmore Drive
Cary, NC 27518
(984) 465-4088

Warren County
• *Warren Hills Rehabilitation & Nursing Center*
864 US Hwy. 158 Business West
Warrenton, NC 27589
(252) 257-2011

Watauga County
The Foley Center at Chestnut Ridge
621 Chestnut Ridge Parkway
Blowing Rock, NC 28605
(828) 386-3300

Yadkin County
Yadkin Nursing Care Center & Magnolias Over Yadkin
903 W. Main Street
Yadkinville, NC 27055
(336) 679-8863

SOUTH CAROLINA

Charleston County
Shem Creek Health Center at South Bay
1400 Liberty Midtown Drive
Mt. Pleasant, SC 29464
(843) 936-2801

Kempton of Charleston
194 Spring Street
Charleston, SC 29403
(854) 500-7778