



# Liberty Healthcare & Rehabilitation Services

*Caring with Excellence*

2334 S. 41<sup>st</sup> Street • Wilmington, NC 28403  
(910) 815-3122 • FAX: (910) 815-3111

## PETITION FOR ADDITION OF ESRD POLICY TO THE 2024 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 41<sup>st</sup> Street, Wilmington, NC 28403  
Email Address: David: [DHolmes@libertyhcare.com](mailto:DHolmes@libertyhcare.com); Timothy: [TWalsh@libertyseniorliving.com](mailto:TWalsh@libertyseniorliving.com)  
Phone Number: (910)-815-3122

### **Background**

Liberty has been taking care of North Carolinians since the late 1800s. The family-owned company began as a small hometown pharmacy in Whiteville, North Carolina. The values, traditions, and trust established by the McNeill family in 1875 continue to be passed down from generation to generation. The principal owners, John A. “Sandy” McNeill, Jr. and Ronnie McNeill, are proud to call North Carolina home, and are the fourth generation of McNeills dedicated to the healthcare industry.

Over the past century, Liberty has expanded from a single retail pharmacy to now offer a broad continuum of care through its’ family of integrated products and services throughout North Carolina, South Carolina, Virginia, Tennessee, Louisiana and Florida. Today, the Liberty family owns, operates, and/or manages nursing homes, home health care and hospice agencies, independent living communities, assisted living communities, continuing care retirement communities, Liberty Medical Specialties (which provides durable medical equipment and infusion therapy services), the Liberty Medicare Advantage HMO insurance plan, and McNeill’s Pharmacy.

Liberty’s comprehensive approach to senior care gives patients, residents, and their loved ones the peace of mind knowing that Liberty understands and can support their needs and lifestyle choices as they age. 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”) requests that a Policy to be added to the 2024 State Medical Facilities Plan (“SMFP”), Policy ESRD-4, which will allow for the development or expansion of a kidney disease treatment

center in skilled nursing facilities across the state. 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 being 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 become an ESRD provider and help address the needs of a growing nursing home population.

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

- Chronic Kidney Disease and ESRD most common in people aged 65 years and older
- Policy addition has the potential for a statewide effect
- Agency and SHCC set precedent when creating Policy ESRD-3
- Larger dialysis organizations are reporting the need for dialysis in SNFs
- Difficulty hospitals face in finding placement for high acute residents including seniors needing dialysis services
- Innovative dialysis technology
- Transportation to outpatient (offsite) dialysis clinics is challenging for nursing home facilities and residents
- Unsustainable contracting models with dialysis centers

#### ***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%<sup>1</sup>. Critically, according to the CDC National Center for Health Statistics, 83.5%<sup>2</sup> 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 2020, 807,920 people in the U.S. were living with end-stage renal disease<sup>3</sup>. Almost 43% of ESRD patients are 65 or older<sup>4</sup>.

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<sup>1</sup> <https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html>

<sup>2</sup> [https://www.cdc.gov/nchs/data/series/sr\\_03/sr03\\_43-508.pdf](https://www.cdc.gov/nchs/data/series/sr_03/sr03_43-508.pdf)

<sup>3</sup> <https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities> (Table 1.2)

<sup>4</sup> <https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities> (Figure 1.10)

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 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.

***Policy addition has the potential for a statewide effect***

In 2022, Liberty presented a similar Spring Petition to the SHCC requesting a similar Policy ESRD-4. The Healthcare Planning and Certificate of Need staff (the “Agency”) recommended denial of Liberty’s Spring Petition, primarily due to the belief that the SMFP’s existing summer petition process was sufficient to allow Liberty to develop the proposed services. The Acute Care Services Committee, while noting support for the notion and acknowledging that this request would be positive for North Carolina residents, voted to accept the Agency recommendation and deny the Petition. Based on the Agency’s and SHCC’s suggestions, Liberty moved forward with a Summer Petition in 2022 for a nursing home dialysis pilot demonstration project of six outpatient dialysis stations in Mecklenburg County. The SHCC recommended denial of Liberty’s 2022 Summer Petition, 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.

However, continuing to submit petitions in the summer for need determinations is problematic. The need for outpatient dialysis stations at nursing homes is not based on just one specific county or even a few specific counties. The troubling circumstances leading Liberty to submit this petition exist statewide nursing homes, and not just in one facility, county or region, which necessitates a new ESRD Policy as opposed to specific county need determinations. Additionally, 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. Though established dialysis providers in North Carolina currently may partner with a nursing home to provide home and/or in-center dialysis services in the nursing home, that approach requires the community-based dialysis center to relocate dialysis stations from an existing facility to the nursing home. Liberty seeks a method to develop new dialysis stations at nursing homes without, in effect, forcing the relocation of existing community-based stations or being forced to partner with an outpatient dialysis provider (under economically onerous terms, as referenced in this petition).

***Agency and SHCC set precedent when creating Policy ESRD-3***

A portion of the analysis of the Agency report for the Liberty 2022 Spring Petition states that “although the Petitioner requested a policy as the means to “open the door” to the provision of dialysis in nursing homes, an existing option currently available to providers is to submit a summer petition to the SHCC for an adjusted county need determination.”

However, neither the Agency nor the SHCC has taken this same position in the past in similar situations. The following is a timeline regarding the creation of Policy ESRD-3, which allows

hospitals to develop kidney disease treatment centers on a hospital campus without the requirement of a need determination.

### **Summer 2019**

1. UNC Hospitals (“UNCH”) submitted a Summer Petition for an adjusted need determination for four outpatient dialysis stations in an acute care setting for Orange County in the North Carolina 2020 SMFP.
2. The Agency, Acute Care Services Committee, and the SHCC recommend approval of the request for an adjusted need determination for four outpatient dialysis stations located on the campus of an acute care hospital in Orange County.

### **November 2019**

1. Governor Roy Cooper sends a Memo approving the 2020 SMFP, which includes a need determination of 4 dialysis stations in Orange County, listed in Table 9D of Chapter 9. A note under Table 9D in reference to the 4 dialysis station need determination includes the following: “In response to a petition, the State Health Coordinating Council approved the adjusted need determination for four outpatient dialysis stations located on the campus of an acute care hospital in Orange County. Certificate of Need shall impose a condition requiring the approved applicant to document that it has applied for Medicare certification no later than three (3) years from the effective date on the certificate of need.”
2. The Certificate of Need Beginning Review Date for the 4 outpatient dialysis stations in an acute care setting for Orange County was set for April 1, 2020. A Certificate of Need Application would be due March 16<sup>th</sup>, 2020.

### **March 2020**

1. The Certificate of Need Application Log for April 1, 2020 Reviews shows that no facility or applicant applied for the four outpatient dialysis stations located on the campus of an acute care hospital in Orange County.

### **April 2020**

1. The Agency proposes Policy ESRD-3 to allow hospitals to develop kidney disease treatment centers (“outpatient dialysis facility”) on hospital campuses without the requirement of a need determination. The Agency moved forward with the Policy proposal allowing development of an outpatient dialysis facility on a hospital campus. According to the Agency request, “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...”

### **October 2020**

1. Governor Roy Cooper sends a Memo approving the 2021 SMFP, which includes the new Policy ESRD-3 ((Development or Expansion of a Kidney Disease Treatment Center on a Hospital Campus).

In summary, after UNC Hospitals filed a Summer Petition for a special need allocation for dialysis stations in Orange County and no one applied to fill that need, the SHCC then proceeded to develop

a statewide Policy, Policy ESRD-3, which allows for the development of outpatient dialysis facilities on a hospital campus.

A mechanism existed in the SMFP through the summer petition process for hospitals to develop outpatient dialysis facilities on a hospital campus, and was utilized by UNC Hospitals. However, no provider ever applied for this additional need determination. Nonetheless, the Agency still moved ahead with the creation of a new Policy. Liberty contends that precedent has been set in the past that the existence of a mechanism in the SMFP, namely the Summer Petition process, does not preclude the SHCC from utilizing the mechanism of approving a new statewide policy.

***Large dialysis organizations are reporting the need for dialysis in SNF's***

NxStage, a subsidiary of Fresenius Medical Care, reports on its website “there are over 520,000 dialysis patients in the United States and approximately 65,000 of them reside in Skilled Nursing Facilities annually.”<sup>5</sup>

DaVita Kidney Care also acknowledges on its website the potential SNF-dialysis benefits, stating a patient will have “improved quality of life” and SNF’s will have “reduced care costs and readmissions”<sup>6</sup> through a dialysis SNF setting.

It is clear that large dialysis organizations see a need for dialysis in SNF’s based on their promotion of their own skilled nursing dialysis programs. However, the opposition comments filed against past Liberty petitions (and expected opposition for this petition) make clear that it is competition that these larger dialysis organizations seek to avoid, even if this Petition would provide the highest quality and best value care to dialysis patients residing in SNF’s. Further, competition is recognized in the basic principles governing the development of the SMFP, in which “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.”<sup>7</sup>

Liberty has been clear throughout each petition that any policy or need determination request is not intended to displace outpatient dialysis facilities in the community. In fact, it is Liberty’s belief that this Policy would be a benefit to the larger dialysis organizations as well as SNF providers. Though established dialysis providers in North Carolina currently may partner with a nursing home to provide home and/or in-center dialysis services in the nursing home, that would require the dialysis provider to relocate dialysis stations from an existing facility to the nursing home (in order to create the den model which Liberty seeks). Liberty seeks a method to develop new dialysis stations at a nursing home without the need for dialysis providers to relocate stations. This Policy would not preclude dialysis providers from collaborating with other SNF providers throughout the

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<sup>5</sup> <https://www.nxstage.com/administrators/snf-facilities/>

Reference to data: DataDialysis.org. FY2017 Dialysis Facility Report Data. 3. Yang A, Lee WY, Hocking K, Xelay Acumen, Inc., Affiliated Dialysis. Survival comparison of daily home hemodialysis vs conventional dialysis in the nursing home setting. Nephrology News & Issues. February 17, 2015.

<sup>6</sup> <https://www.davita.com/partners/skilled-nursing-facilities>

<sup>7</sup> [https://info.ncdhhs.gov/dhsr/ncsmfp/2023/2023\\_SMFP\\_COMPLETE\\_v3\\_w\\_covers\\_signed\\_sec\\_memo\\_signed\\_gov\\_approval.pdf](https://info.ncdhhs.gov/dhsr/ncsmfp/2023/2023_SMFP_COMPLETE_v3_w_covers_signed_sec_memo_signed_gov_approval.pdf) (Chapter 1, Basic Principles Governing the Development of the SMFP, pages 3-4)

state. Liberty is simply proposing a Policy whereby a SNF provider is not forced to partner with an outpatient dialysis provider and may develop its own dialysis program.

***Difficulty hospitals face finding placement for high acute residents***

Hospitals frequently 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 many patients with multiple comorbidities. Therefore, upon discharge from the hospital, 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 nursing, therapy and dialysis care would be a clinical innovation. Same-location care would allow for safe delivery of dialysis services, better coordination 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 negative impact on patient routine and socialization opportunities; infections; bodily wear-and-tear; and van or ambulance accidents; among others.

***Innovative dialysis technology***

If this Petition is approved, and Liberty applies for and obtains a CON under the new policy, 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, designed to offer a better experience for patients and providers. As an innovative technology, the Tablo machine comes with the following features:

1. Wireless Connectivity, allowing 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. Cartridge, 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, ensuring that patients and providers have access to the latest optimizations without the need to replace existing hardware.

9. Flexible treatment duration, ranging 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 and/or similar technology that is available in the market, North Carolina SNFs 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 technologies; and
- Use of safe tap water, eliminating reliance on expensive water treatment facilities.

While Liberty plans to use a state-of-the-art Tablo dialysis machine to deliver high-quality dialysis treatment, other applicants may use a different technology. The important part is that there is technology out there that SNFs can use to deliver high quality, safe dialysis.

***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 critical. 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 appointments. 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. There currently is no state or federal reimbursement mechanism for SNFs which have to incur these transportation costs.

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.

Most importantly, 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 would greatly benefit residents and nursing home operators, with transportation risks and costs greatly reduced while offering better coordination of care and a much improved patient experience.

***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 pursuant to 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 SNF 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<sup>8</sup> own the outpatient dialysis facility.

***Previous Public Comments Filed in Opposition to Liberty’s Petition***

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<sup>8</sup> 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.



In the 2022 Spring and Summer petitions filed by Liberty, a number of commenters consisting primarily of existing non-SNF dialysis providers, filed comments in opposition to Liberty's Petition. The majority of these opposing comments focused on the issue of quality of care and suggested that providing dialysis services to SNF residents at the nursing facility as proposed in Liberty's Petition raised quality of care concerns.

Liberty respectfully disagrees with these comments. In fact, one of the driving factors behind Liberty's petition is the well-documented negative physical and emotional risks to SNF residents from being loaded into vans multiple times each week for transport to nearby dialysis centers where they often wait extended periods of time for treatment, endure the long dialysis process, miss meals, become exhausted and return to the nursing facility too depleted to eat or take part in activities. The fact that several other states permit the precise type of dialysis in nursing facilities being proposed by Liberty indicates that those states have found this type of care to be safe for nursing facility residents. Liberty also notes the following points that address the quality of care issue:

- The proposed services will be provided via an approved ESRD provider who is responsible for the provision of all equipment, supplies and staff. Only ESRD employees may perform dialysis activities, and only the ESRD staff RN is permitted to initiate and terminate the dialysis treatment. Numerous other requirements for both the ESRD provider and facility designed to ensure the safe and effective delivery of care are detailed in regulations governing these services issued by the U.S. Centers for Medicare and Medicaid Services.
- There have been a number of articles and studies reported in reputable publications documenting the safety of the model being proposed by Liberty. See, for example, the following article: <https://www.bkd.com/alert-article/2020/03/nursing-home-based-hemodialysis-opportunity-broaden-snf-patient-populations>
  - The model proposed by Liberty is not new and has been successfully implemented in other states, As of 2020, at least 25 states offer either home hemodialysis or in-center dialysis in skilled nursing facilities.
- Illinois appears to be the most comparable model, as Illinois regulates kidney disease treatment centers, but provides an exemption for dialysis units.
  - During the preparation of its petition to the SHCC, Liberty reached out to health care regulators in Illinois. Liberty was informed by Mike Constantino, Public Service Administrator for Illinois, that Illinois allows SNFs to provide dialysis services in SNFs and that they require no CON. Rather, SNFs are permitted to obtain an Exemption to provide these services. Mr. Constantino told Liberty: "I can tell you since 2018 we have seen more nursing homes ask for that exemption and usually it is for four stations."
- Further, the CON application form which any entity seeking a CON under the proposed new policy would have to complete, includes multiple questions which require the application to demonstrate how it will ensure quality and further the goals of access, cost and quality of care. As such, the CON Section has the authority to ensure that any proposal filed under the proposed new policy includes mechanisms and safeguards to ensure safety and achieve quality of care. The CON Section also has the power to impose conditions upon its approval of a CON applicant's approval. In short, the CON Section has the legal authority to review any CON application filed under the proposed new policy to ensure

that any concerns about quality of care and patient safety are addressed and satisfied. The comments filed by community-based opponents of Liberty’s prior petitions alleging quality-of-care concerns are without foundation and should be recognized for what they are—competition-based comments. Liberty’s focus in this petition is on the safety of SNF residents across the State and how to deliver to them the highest quality of care in the safest, least disruptive environment.

### ***Conclusion***

Liberty believes the Policy presented should be incorporated into the 2024 SMFP for the benefit of our State’s most vulnerable citizens, those residing in skilled nursing facilities and respectfully requests that the SHCC vote to approve Liberty’s Petition.

#### **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 again for an adjusted need determination in specific service areas/counties, as was done in the Summer 2022 Petition. However, as stated above, 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.

##### *Include ACH facilities in proposed Policy ESRD-4 Policy*

As discussed on page 1, Liberty is an experienced healthcare provider, which includes the operation of assisted living facilities (in addition to the skilled nursing facilities it operates). 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**

There are currently no outpatient dialysis stations located within a nursing home in North Carolina. Further, as discussed above, 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 the needs 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 the aim of the 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.” Adding this Policy to the SMFP would permit better collaboration of care, result in fewer hospital readmissions, and help build 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 stress that 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. A licensed nursing home facility shall propose to develop at least the minimum number of stations required for Medicare-certification by the Centers for Medicare and Medicaid (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 applicable to dialysis facilities if located within the nursing home or “proximate to the nursing home building;”.

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.