Liberty Healthcare
& Rehabilitation Services
Caring with Excellence

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

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

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Background

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

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

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

2. **Statement of Requested Change**

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

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

3. Reasons for the Proposed Change

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

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

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

Advancing American Kidney Health initiative

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

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

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

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

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

Basic Principles outlined in Chapter 9 of the SMFP

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

"Basic Principles

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

Similar to hospitals and their permitted use of outpatient dialysis clinics under Policy ESRD-3, Liberty and other nursing homes throughout the state have the necessary infrastructure to house outpatient dialysis stations, and therefore would request to waive the requirement for a new dialysis facility to have at least 10 stations.

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

Innovative dialysis technology

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

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

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

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

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

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

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

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

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

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

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

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

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

With nearly four in ten seniors affected by chronic kidney disease and 43% of ESRD patients being 65 and older, many skilled nursing patients are or will be in need of dialysis. However, traveling to offsite dialysis can be very disruptive to the health and welfare of this population, most of whom are already frail and often have multiple health problems. The intent of the proposed policy will enable nursing homes to meet the needs of this vulnerable population by eliminating the necessity for uncomfortable patient transports, lengthy patient wait times and treatments at off-site dialysis center disrupting patient care, meals and comfort.

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

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

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

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

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

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

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

Unsustainable contracting models with dialysis centers

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

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

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

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

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

CON regulation of dialysis facilities in other states

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

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

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

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

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

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

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

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

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

Liberty Dialysis Experience

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

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

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

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

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

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

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

a. Statement of the Adverse Effects if Change Not Made

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

b. Statement of Alternatives to the Proposed Change

Liberty has discussed several possible alternatives. These included:

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

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

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

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

Include ACH facilities in proposed Policy ESRD-4 Policy

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

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

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

Since there are currently no outpatient dialysis stations located within a nursing home in North Carolina, this proposed 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. <u>Evidence Requested Change is Consistent with Three Basic Principles Governing the Development of the SMFP (Safety and Quality, Access and Value)</u>

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

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

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

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

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

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

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

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

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

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

ATTACHMENT 1

PROPOSED POLICY ESRD-4

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

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

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

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

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

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

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

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