



Wake Forest Outpatient Dialysis
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August 4, 2023

Healthcare Planning Section
Division of Health Service Regulation
NCDHHS
809 Ruggles Drive
Raleigh, NC 27603

Re: Health Systems Management's Comments on behalf of Wake Forest University Health Sciences Dialysis Centers Comments Regarding Liberty Healthcare's Petition to modify Chapter 9 of the 2024 State Medical Facilities Plan – Halifax County

Dear SHCC Members:

On behalf of the Wake Forest University Health Sciences (WFUHS) Dialysis Centers, WFUHS presents the following observational comments regarding the petitions filed by Liberty Healthcare ("Liberty") relating to a change in need methodology for dialysis stations in North Carolina counties.

INAPPROPRIATE FILING TIME

The 2023 SMFP clearly states on page 7 the following: "**Spring petitions and proposals. Spring petitions involve requests for changes to the SMFP that have potential for a statewide effect, such as the addition, deletion or revision of policies or need determination methodologies.**" Clearly, all the petitions submitted by Liberty represent such a change and therefore are ineligible for consideration at this late date.

POLICY CHANGE REQUEST

By its own words, Liberty proposes a "**modification to Chapter 9 of the SMFP.**" Liberty's proposed modification, while being filed untimely, also violates the basic principles of CON. Liberty's petitions are clearly an attempt to circumvent the existing CON laws regulating the establishment of a new institutional health service. Particularly, Liberty is requesting the creation of a "hybrid" SNF / ESRD treatment facility, which would be subject to both SNF and ESRD rules and regulations.

RULE MAKING ESRD COMPLY WITH SNF REQUIREMENTS

Liberty's proposal asks that the special need determination require the SNF / ESRD provider to be located within or on the same campus as the SNF. If located within the SNF, Liberty asks that the SHCC establish an additional new rule that would require the dialysis unit to comply with "**federal life safety and building code requirements applicable to a nursing home.**" Such requirements are not necessarily compliant with CMS Rules for Participation relating to ESRD treatment facilities nor within the realm of authority of the SHCC to create.

EXCLUDE SNF / ESRD STATIONS FROM COUNTY STATION TOTALS

Liberty goes on to suggest that any stations developed pursuant to this new rule would be excluded from the county and facility need methodologies. However, CMS standards provide that any patient with ESRD would be able to utilize those stations. The result would be a duplication of dialysis services for SNF and non-SNF patients. Such a rule would also violate a patient's right to choose their ESRD provider and thereby also pose a potential violation of STARK laws in regard to self-dealing.

LIMIT WHO CAN APPLY

NC CON statutes allow any Halifax to apply for a published need determination, however, Liberty proposes a policy change / new policy creation that would allow only "***a licensed nursing home facility***" to apply for a SNF / ESRD need determination. To be clear, ESRD is a provider type that is separate and unique from a SNF. This ask is the equivalent of a dialysis provider requesting a special need determination to allow it to develop SNF beds in an ESRD unit.

CREATE A NEW NEED POLICY

Liberty puts forth what it calls "***quantifying data***" including per its petition: "***Halifax SNF Dialysis Data, Nursing Home ESRD Dialysis Station Need Determination by Planning Area, and Comparison to State and National Averages.***" Liberty references the UM-KECC ESRD patient database and how it used Medicare Dialysis Facilities Data – FY 2023, Medicare Dialysis Facilities Data Dictionary, and the 2023 SMFP to determine that Halifax County has a need for 10 ESRD stations located at a nursing home. Liberty did this by suggesting that since 15.57% of patients on dialysis are SNF residents and since Halifax County had 212 SNF residents as of 12/31/2021, there were 33 SNF residents who needed dialysis stations at a SNF in Halifax County "***during the year.***" Thus, according to Liberty, Halifax County needs 10 more dialysis stations to serve the SNF residents at a SNF / ESRD provider.

All the SNF / ESRD residents in Halifax County requiring dialysis already have their needs met at existing ESRD treatment facilities. This is further evidenced by the 4-station county surplus published in the 2023 SMFP. Based on its erroneous assumptions, Liberty goes on to form an entire need determination procedure, to quantify its projected need for a total of 11 SNF / ESRD stations.

FACTUAL INFORMATION

In all its petitions Liberty has never identified how many **Liberty patients**, specifically, required ESRD services in the past. Liberty operates 1 of the 4 SNF's in Halifax County. Yet, Liberty is the only SNF provider requesting SNF / ESRD stations. Liberty is making its requests without providing how many, if any, ESRD patients it sends to dialysis during any time referenced in its petition.

Liberty fails to explain that its SNF / ESRD patients do not necessarily live at the SNF for the remainder of their lives. Thus, the overall need for ESRD treatment for SNF patients is far less than presented by Liberty. Per the 2023 SMFP, there were 242 ESRD patients in Halifax County, which includes SNF residents receiving dialysis care. The two existing ESRD treatment facilities are operating at less than 78% utilization. The need projected by Liberty is both unwarranted and unfounded.

Liberty suggests that its request is necessary because all its prior petitions were denied. However, that is incorrect. Liberty's request for a pilot program in Mecklenburg County was granted by the SHCC. Applications for that special need determination are due to the CON Section by September 15, 2023. Thus, the pilot program allowed by the SHCC for Mecklenburg County is still in its pre-development stage and no conclusions can yet be drawn on its long-term viability.

SCHEDULING COMPLAINTS

On page 7, Liberty proposes that by providing dialysis within the nursing home, clinical patient outcomes would improve because the SNF could schedule the dialysis treatment around the patient's SNF schedule versus scheduling SNF services around dialysis. However, there are clinical reasons patients are given dialysis on a consistent schedule (M,W,F or T,Th,S / mornings or afternoons), which may be outside the realm of understanding to those who do not possess expertise in the field of ESRD treatment. Based on more than 40 years of experience and expertise in the treatment of ESRD patients, consistency is key to patient longevity and patient quality of life.

INFECTION RISK & PATIENT SATISFACTION

On Page 8 of its petition, Liberty claims its proposal maximizes Safety and Quality because "***it reduces the risk of infection and complications associated with offsite travel.***" However, Liberty fails to show any evidence that the existing ESRD providers pose a risk to patient safety or an increase in the rate of infection. Liberty also fails to show how its proposal would mitigate any potential ESRD-related infection risks and offers only a subjugated opinion as evidence.

Liberty suggests that overall SNF patient satisfaction would increase. However, given Liberty's lack of experience in the specialized care required to successfully deliver ESRD treatments patients may be less satisfied due to risk of inadequate dialysis and a reduction in their overall quality of life.

PERFORMANCE

The most recent CMS report for skilled nursing facilities found at <https://data.cms.gov/provider-data/topics/nursing-homes> indicates Liberty as well as other SNF's may be ill-equipped to comply with ESRD CON requirements. Section O of the ESRD CON application requires all applicants to provide survey data for all commonly owned entities during an 18-month lookback period. Since Liberty is asking for a new hybrid SNF / ESRD provider type and wants the SHCC to require the ESRD portion to comply with SNF standards, it is reasonable to expect the SNF to comply with ESRD standards. Thus, the surveys conducted at every like-owned SNF would be applicable in determining if the applying SNF could be reasonably expected to safely deliver dialysis care. See **Exhibit A**.

FINANCIAL CONCERNS

Liberty states on Page 7 of its petition the adverse effects if a change is not made to allow their petition. Twice in the same paragraph, Liberty complains that taking patients to dialysis is not "***economically affordable for the nursing facility***" and that transporting patients to dialysis is a "***cost burden on the nursing home.***"

Liberty suggests on page 9 that by allowing an 11-station duplication of the existing services in Halifax County, access to dialysis care for SNF patients would be improved. However, Liberty **fails** to show any barriers to ESRD care for SNF patients aside from its **own financial burden** of providing transportation services to its patients suffering from ESRD. Liberty also fails to indicate how many, if any, of its patients required dialysis and transportation services during any period discussed in its petition. Perhaps, Liberty in its quest to diversify its business offerings, should develop a new transportation service exclusively for ESRD patients to and from treatment. Liberty could use that service as means to overcome the financial burden of paying another transportation provider, which Liberty continues to stress is a barrier to finding true value.

Liberty's proposal would also limit the SNF patient's choice by basically requiring patients to use their in-house dialysis versus allowing the patient to choose their own nephrologist who may not be affiliated with the Liberty SNF.

CONCLUSION

In Halifax County the existing ESRD providers do a very good job addressing patient station needs as evidenced by the 4-station county surplus as recorded in the 2023 SMFP. Liberty sees these continued petitions as its only means by which to enter the ESRD industry and circumvent the CON requirements by which all legitimate ESRD treatment providers are bound. To allow any of Liberty's petitions would be an injustice. The existing ESRD treatment facilities and providers who have operated for decades within the boundaries of CON have spread access to dialysis services to nearly all of North Carolina's 100 counties. To this end and for the reasons mentioned above, it is our hope that the SHCC will deny all the petitions filed by Liberty for the 2024 SMFP to protect the health and safety of the ESRD patients of North Carolina.

Respectfully,

C. Alex Kemp, II

C. Alex Kemp, II, MBA
Chief Executive Officer
Health Systems Management, Inc.

Marshia S. Coe

Marshia S. Coe, RN, BSN, MSHA
Chief Operating Officer
Health Systems Management, Inc.

Affiliated Name	Legal Name	Provider Name	Abuse Icon	Total Fines	Substantiated Complaints
LIBERTY SENIOR LIVING	CAROLINA BAY HEALTHCARE CENTER OF WILMINGTON, LLC	BRADLEY CREEK HEALTH CENTER	N	\$ -	0
	Legal Business Name Not Available	HIGHLAND HOUSE REHABILITATION AND HEALTHCARE	Y	\$ 28,217.99	11
	LIBERTY COMMONS NURSING CENTER INC	LIBERTY COMMONS REHABILITATION CENTER	Y	\$ 22,307.35	4
	LIBERTY HEALTHCARE GROUP, LLC	BERMUDA COMMONS NURSING AND REHABILITATION CENTER	N	\$ -	8
		CAPITAL NURSING AND REHABILITATION CENTER	N	\$ 7,621.25	4
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		INN AT QUAIL HAVEN VILLAGE	N	\$ 116,432.75	10
		LIBERTY COMMONS N&R CTR OF COLUMBUS CTY	N	\$ 83,057.00	3
		LIBERTY COMMONS NRSG & REHAB CNTR OF SOUTHPORT LLC	N	\$ 26,675.19	4
		LIBERTY COMMONS NSG & REHAB CTR OF ROWAN COUNTY	Y	\$ 3,250.00	1
		LIBERTY COMMONS NSG & REHAB CTR OF JOHNSTON CTY	N	\$ 42,524.00	35
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		LIBERTY COMMONS NSG AND REHAB CTR OF LEE COUNTY	Y	\$ 251,859.66	26
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LIBERTY SENIOR LIVING Total			5	\$ 1,526,454.86	317

EXHIBIT A

August 4, 2023

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NCDHHS
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Respectfully,

A handwritten signature in black ink, appearing to read "Russell M. Howerton MD". The signature is fluid and cursive, with a large, stylized initial "R".

Russell M. Howerton, MD, FACS
President Wake Forest Health Network
Senior Vice President Clinical Operations
Atrium Health Wake Forest Baptist

Affiliated Name	Legal Name	Provider Name	Abuse Icon	Total Fines	Substantiated Complaints
LIBERTY SENIOR LIVING	CAROLINA BAY HEALTHCARE CENTER OF WILMINGTON, LLC	BRADLEY CREEK HEALTH CENTER	N	\$ -	0
	Legal Business Name Not Available	HIGHLAND HOUSE REHABILITATION AND HEALTHCARE	Y	\$ 28,217.99	11
	LIBERTY COMMONS NURSING CENTER INC	LIBERTY COMMONS REHABILITATION CENTER	Y	\$ 22,307.35	4
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LIBERTY SENIOR LIVING Total			5	\$ 1,526,454.86	317

EXHIBIT A

August 9, 2023

Dr. Andrea Emmanuel, Interim Assistant Chief Healthcare Planning
Mr. John Young, Chair, Acute Care Services Committee
Dr. Charul Haugan, Vice-Chair, Acute Care Services Committee
Ms. Elizabeth Brown, Planner
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Fresenius Medical Care's Comments Opposing Liberty Healthcare and Rehabilitation Services Petition for a County Need Determination for Outpatient Dialysis Stations at a Nursing Home Facility in Alamance, Bertie, Brunswick, Buncombe, Chatham, Columbus, Cumberland, Davie, Durham, Forsyth, Franklin, Halifax, Johnston, Lee, Mecklenburg, Moore, New Hanover, Orange, Person, Robeson, Rowan, Sampson, Wake and Watauga Counties in the 2024 State Medical Facilities Plan

Dear Acute Care Services Committee Members:

Fresenius Medical Care Holdings, Inc., (parent company of the Fresenius Medical Care related entities¹) d/b/a Bio-Medical Applications of North Carolina, Inc. (BMA), offers the following comments opposing Long-Term Care Management Services, LLC d/b/a Liberty Healthcare and Rehabilitation Services ("Liberty") "Petitions for County Need Determinations for Outpatient Dialysis Stations at a Nursing Home Facility in the 2024 State Medical Facilities Plan" ("Liberty's Summer 2023 Petition"). Liberty's Summer 2023 Petitions are requesting the following number of stations in the following counties:

- Alamance County: Thirteen (13) Stations
- Bertie County: Four (4) Stations
- Brunswick County: Six (6) Stations
- Buncombe County: Sixteen (16) Stations
- Chatham County: Four (4) Stations
- Columbus County: Four (4) Stations

¹ Bio-Medical Applications of North Carolina, Inc., Bio-Medical Applications of Fayetteville, Inc., Bio-Medical Applications of Clinton, Renal Care Group of the South, Inc., RAI Care Centers of North Carolina II, LLC and several joint venture operations in North Carolina: Carolina Dialysis, LLC, FMS ENA Home, LLC, Fresenius Medical Care of Lillington, LLC, Independent Nephrology Services, Inc., Fresenius Medical Care of Morrisville, LLC, Fresenius Medical Care of Rock Quarry, LLC, and Fresenius Medical Care of White Oak, LLC.

- Cumberland County: Twenty-Eight (28) Stations
- Davie County: Four (4) Stations
- Durham County: Thirty-Four (34) Stations
- Forsyth County: Thirty-Eight (38) Stations
- Franklin County: Eight (8) Stations
- Halifax County: Eleven (11) Stations
- Johnston County: Fourteen (14) Stations
- Lee County: Eight (8) Stations
- Mecklenburg County: Fifty-Nine (59) Stations
- Moore County: Seven (7) Stations
- New Hanover County: Seventeen (17) Stations
- Orange County: Seven (7) Stations
- Person County: Six (6) Stations
- Robeson County: Seven (7) Stations
- Rowan County: Seven (7) Stations
- Sampson County: Six (6) Stations
- Wake County: Fifty-Seven (57) Stations
- Watauga County: Four (4) Stations

Liberty's Summer 2023 Petitions are requesting a total of 369 stations in 24 different counties across the state.

Introduction

(BMA), owns, operates and/or manages over 100 existing and or approved North Carolina dialysis facilities and provides in-center hemodialysis (ICHHD) as well as training and support for both home hemodialysis (HHD) and peritoneal dialysis (PD) modalities, to over 10,000 dialysis patients across the state of North Carolina.

BMA is keenly sensitive to patient safety and quality, clinical outcomes, patient satisfaction, and adequate access to dialysis care. For at least the past decade, BMA has sought CON approval to develop new dialysis facilities and add additional stations to our clinics in North Carolina for the sole purpose of enhancing access to care by reducing the barriers that come with dialysis treatment. **Existing dialysis providers who are certified, experienced, and continuously trained to offer home hemodialysis (HHD) training and support services have the ability to go into settings like nursing homes to offer staff assisted home hemodialysis.** To be clear, BMA's concerns with Liberty's petitions is not competition. The patients that Liberty intends to offer dialysis are patients who are currently in an existing dialysis facility. Patients that we see, know and love. Their safety and well-being is our utmost priority. While it is honorable that Liberty wants the ability to offer dialysis services on-site to its patients, the fact that these services are already being offered by dialysis providers should not be ignored.

Staff Assisted Home Hemodialysis

The dialysis equipment described in Liberty's 2022 Spring and Summer and 2023 Spring petitions looks to be the same or similar to what is often used to treat HHD patients once their training is complete. This type of equipment is different from what is typically used in an in-center dialysis facility, mostly because of the cost and maintenance associated with the water system required to operate machines at an in-center dialysis facility. Thus, it is reasonable to conclude that what Liberty is proposing to offer to its nursing home patients is HHD, given the patients residence is the nursing home. However, because of the acuity level of many of these patients, administering their own dialysis treatment is not an option without assistance. What Liberty has essentially been proposing in each of its petitions is for nursing home providers to be able to offer staff assisted HHD for its nursing home patients instead of collaborating with an existing dialysis provider for these services.

Staff assisted HHD in a nursing home is typically done in a den model. In this model, the nursing home provider will designate space within or on-site at their facility that will be used to dialyze nursing home residents. This space typically includes patient chairs, TVs, and the dialysis equipment. On the day that patient(s) are receiving treatment, a member of the nursing home staff would bring the patient(s) to the designated area for treatment and a dialysis facility certified to offer HHD would provide the staffing to assist the patients with treatment. Approval of these petitions would allow Liberty and other nursing home providers to bypass the offering of these services by existing dialysis providers because they would be doing so themselves.

Liberty's 2023 Summer Petition

In support of its 2023 Summer Petition, Liberty relies on many of the same arguments it provided in previous petitions, however, Liberty also includes quantitative information that it states supports its newest request. BMA firmly stands behind its comments made on previous petitions but would also like to reiterate additional reasons why this petition should also be denied.

BMA believes that Liberty's Summer 2023 Petition should be denied for the reasons outlined throughout these comments.

2023 Adjusted Need Determination for Six (6) Stations in Mecklenburg County

Liberty's Summer 2023 Petition follows three other petitions, summarized below:

- 2022 Spring Petition: requested the creation of a new policy, Policy ESRD-4, to allow the development or expansion of a kidney disease treatment center at a skilled nursing facility
- 2022 Summer Petition: requested the creation of a nursing home pilot demonstration project for six (6) outpatient dialysis stations in Mecklenburg County

to be located at “Royal Park of Matthews Rehabilitation and Health Center” (“Royal Park”)

- 2023 Spring Petition: requested the creation of a new policy, Policy ESRD-4, to allow the development or expansion of a kidney disease treatment center at a skilled nursing facility

Each of the petitions previously submitted were denied, however, the Agency recommended an alternative to Liberty’s 2022 Summer Petition, which was an adjusted need determination for six (6) outpatient dialysis stations located at a nursing home facility in Mecklenburg County. The Agency’s recommendation for an adjusted need determination for six (6) outpatient dialysis stations located at a nursing home facility in Mecklenburg County was approved by both the Acute Care Services Committee and the SHCC and the need determination is included in Table 9C: Dialysis Station Need Determination County Need Determination Methodology in Chapter 9 of the 2023 SMFP. The applications for this need determination are due to the CON Section by 5pm on September 15, 2023, and the review is scheduled to begin on October 1, 2023. Since this review has not begun and thus no decision has been made on these applications, BMA suggests that the most reasonable response is to deny Liberty’s Summer 2023 Petitions to give opportunity for a decision to be rendered on the applications that will be filed pursuant to the 2023 Adjusted Need Determination in Mecklenburg County. A decision on these applications will be rendered before the Spring 2024 SHCC meeting and would allow for petitions to be filed to change the need methodology at that time.

Further, Condition #5 of the adjusted need determination for six (6) stations in Mecklenburg County in the 2023 SMFP states,

“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.”

While it has been stated that these stations will be excluded from the planning inventory in the SMFP, it is not clear whether the patients utilizing these stations will be included or excluded in the initial ratios for average rates of use that project the total number of patients, which impacts future facility and county need methodology determinations.

Existing ESRD Need Methodologies in the SMFP

As you know, there are two existing methodologies in Chapter 9 of the SMFP for “End-Stage Renal Disease” (“ESRD”) services, a facility need methodology which projects need for a specific facility and a county need methodology which projects need for a specific county. When a facility need determination exists, only the facility that generated the need may apply for a certificate of need (CON) to add stations. When a county need determination exists, any current provider may apply for a CON to add stations in an existing facility or develop stations at a new facility, and a provider who is not currently offering these services may also apply to develop these stations at a new facility. The facility need methodology is based on facility specific patient data and the county need

methodology is based on county specific patient data. A county's total ESRD patient population is essential to calculating the "Average Annual Rate Change" ("AARC") used to project future patient populations and station need. Patients who are residents of nursing home facilities are included in both methodologies in the SMFP for ESRD services. **Liberty's 2023 Summer Petition essentially extracts the nursing home dialysis patient population "it believes" is receiving treatment at existing dialysis facilities from the total ESRD patient population and applies the county need determination methodology that is already being applied by the standard methodology, in order to project the number of outpatient dialysis stations for each of the 24 counties identified in its petitions, which is unnecessary and duplicative.**

Annually, ESRD providers report data for each dialysis facility on the current number of certified dialysis stations and the current number of dialysis patients at the facility by county and modality. While the data reported to Healthcare Planning is self-reported, it is the data that the Agency relies on and uses to apply both the facility and county need methodologies that identify need determinations in the SMFP each year. This data is reviewed by Healthcare Planning, the Acute Care Services Committee, the SHCC and ultimately the Governor prior to being included in the SMFP.

This information was last collected on December 31, 2022, and reported to Healthcare Planning in February 2023 and will follow this same process before it is included in the Approved 2024 SMFP. The reporting period for the data that Liberty is relying on in its 2023 Summer Petition is for December 31, 2021. December 31, 2021 facility data was reported to Healthcare Planning in February 2022 and was used to develop the 2023 SMFP, thus the data that Liberty is relying on is for the previous planning year and is not the most accurate information to use for an adjusted need determination in the 2024 SMFP. The data that Liberty is relying on has also not been vetted by the established processes of the SHCC and could be inaccurate, inflated and simply unreliable.

Liberty's Nursing Home Dialysis Patients

On page 8 of Liberty's 2022 Spring and Summer petitions it was stated,

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

While there may be a need for more on-site dialysis services at nursing homes throughout the state in the future, it is evident by Liberty's own admission that the current number of dialysis nursing home residents that Liberty has is still relatively small. To be exact, 80 nursing home dialysis patients compared to the 19,090 total ESRD patient population, as stated in the Chapter 9: Dialysis Data by County of Patient Origin Report in the Proposed 2024 SMFP, is only 0.4% of the total ESRD patient population. **Such a small percentage of the total ESRD patient population being residents of a nursing home does not support an additional 24 county need determinations for a total of 369 stations in the 2024 SMFP.**

Nursing Home Dialysis Patient Population

Since the filing of Liberty's 2023 Summer Petition, BMA investigated the number of nursing home patients at its dialysis facilities in Alamance, Bertie, Brunswick, Chatham, Cumberland, Durham, Franklin, Halifax, Johnston, Lee, Mecklenburg, Orange, Robeson, Sampson, Wake and Watauga counties. In Exhibit 4 of each of Liberty's petitions, they reported the number of nursing home facility patients at existing dialysis facilities as of December 31, 2021. For BMA, Liberty reported a combined total of 630 nursing home patients at facilities in the counties listed above. However, as of July 31, 2023, our own internal data shows that BMA facilities have approximately 230 nursing home patients at its facilities, a difference of 400 patients compared to what Liberty reported in its petitions. BMA acknowledges that the reporting period for the number of nursing home patients at BMA facilities referenced above is different from the reporting period relied upon by Liberty, however, BMA and other dialysis providers would know better than Liberty the number of nursing home dialysis patients it actually has at its facilities. In addition, A difference of 400 patients is evident that Liberty's Summer 2023 Petition does not consider the number of nursing home patients who may be short stay residents due to rehab and not long-term care patients. Not considering this information can lead to an inflated number of nursing home dialysis patients.

Medical Director Oversight of a Dialysis Facility

BMA would like to emphasize how in depth and collaborative the offering of dialysis services is. It is not enough to just "identify a need" or purchase the latest technology. None of what we do would be possible if it was not for the skill, training, and expertise of our staff. **BMA is respectfully requesting that the Acute Care Services Committee and the SHCC consider not only the concerns of transporting nursing home patients off-site to dialysis three times a week, but also the concerns of the nephrologist and medical directors who would have clinical oversight over this type of facility and patients.** BMA has existing relationships with several nephrology practices throughout the state and what we know from our relationships with them is that their manpower, as with many other healthcare positions, is limited. Simply, the demand for medical directors exceeds the number of available physicians who can provide oversight. This is the primary reason why BMA has been delayed in offering more staff assisted HHD at nursing home facilities.

The "Centers for Medicare and Medicaid Services" ("CMS") states in its Conditions for Coverage that to provide dialysis services, a multitude of staff is needed, including but not limited to:

- Medical Director
- Nurse Manager
- Self-Care and Home Hemodialysis Training Nurse
- Patient Care Dialysis Technician

Each of these individuals have a specialized skill set, training, and expertise, specifically in ESRD and dialysis care, that allows them to care for dialysis patients. Nursing home providers are simply not positioned to employ this type of specialized staff for the benefit of such a small dialysis patient population. Even Liberty acknowledges in its 2023 Spring Petition the importance of these requirements and references a memo from CMS on home dialysis services in a Long-Term Care (LTC) facility, which requires that home dialysis in a nursing home be administered and supervised by the personnel referenced above who meet the criteria for qualifications, training, and competency by way of a written agreement between the nursing home and the ESRD facility. Thus, even CMS recognizes that nursing homes are simply not equipped to offer dialysis services without the oversight of an experienced ESRD provider. Liberty has again failed to address how they intend to overcome the current challenges facing medical oversight as a dialysis provider.

Staffing Shortages

In addition to nephrology and medical director coverage, staffing is also challenging with nursing and tech positions both locally and nationally. Specialized nurses and techs are a necessity in the offering of dialysis services and is even more of a necessity for high acuity level nursing home patients. If an existing dialysis provider is experiencing challenges finding qualified staff for our facilities, certainly a nursing home provider not experienced in the offering of dialysis services will also face the same challenges. Liberty has not addressed how they will acquire the staff qualified to operate a dialysis facility.

FMC Aldersgate

In 2015, BMA filed an application to develop a new 10-station dialysis facility, Fresenius Medical Care Aldersgate (FMC Aldersgate) in Charlotte by relocating six dialysis stations from FMC Charlotte and four dialysis stations from BMA West Charlotte. Aldersgate is a continuing care retirement community (CCRC) offering assisted living, skilled nursing, memory care, rehabilitation services and home care. A letter from the CEO was included in the Aldersgate CON application that stated,

“On-site dialysis care will be a tremendous benefit for our resident population which may have need for these services. Dialysis services on campus will eliminate the need for our patients to travel off campus three days a week for their care. This will obviously reduce the financial burden associated with travel to and from dialysis care.”

While CCRCs are not the same as a nursing home, they do offer skilled nursing services as part of their continuity of care model. Thus, the offering of dialysis services on-site at a long-term care facility has been done before through a collaborative effort between an existing long-term care provider and an existing dialysis provider. As stated, this facility was not developed pursuant to a county need determination from either the standard

methodology or an adjusted need determination and shows BMA's commitment to offering dialysis specifically with nursing home patients in mind.

Comments on Previous Petitions

Several comments have been filed by physicians on Liberty's 2022 Spring and Summer and 2023 Spring Petitions that BMA respectfully request be reconsidered. The following excerpts are from comments filed on Liberty's Spring 2022 petition:

Dr. Eric Raasch, MD with NC Nephrology, PA provided the following comments,

"The application describes a "state-of-the-art dialysis machine (unnamed)", but there exists no explanation of how "Liberty" will deliver dialysis to their patients. I find no description of planning for staff, such as nurses trained in dialysis, patient care technicians trained in dialysis, or attending nephrologists, mentioned in the proposal. The provision of dialysis represents a complex medical procedure. Dialysis requires certified care providers and the oversight of Board-Certified Nephrologists. Without the proper staff and oversight, "Liberty" does not demonstrate how they will ensure patient safety. As a result, this proposal represents a risk to ESRD patients who reside in a skilled nursing facility, and this risk outweighs any benefit to the "patient experience" related to "reducing travel time."

Drs. Harmeet Singh, Munsoor Lateef and Sarath Kolluru with Central Carolina Kidney Associates, P.A. provided the following comments,

"Portable dialysis machines with newer technology can be utilized to provide dialysis at home and other settings. However, home hemodialysis patients are carefully selected. They are relatively healthier with much fewer co-morbid illnesses."

The comments above clearly articulate the concerns of the physicians, the same physicians who would ultimately have oversight over a dialysis facility and the patients. One thing to emphasize is that just because dialysis can be offered on-site at a nursing home facility does not mean that every nursing home dialysis patient would be a good candidate for on-site treatment. Because of the acuity level of these patients, the physician would be the one to determine if it is medically appropriate to dialyze these patients in this way, not Liberty as a nursing home or dialysis provider.

Unnecessary Duplication of Existing and Approved Services

Liberty's 2023 Summer petition does not contain any evidence that the current capacity of stations in the county is insufficient to meet the needs of the nursing home dialysis patient population in the service area the respective service area.

A CON application pursuant to a county need determination in a county where there is excess capacity would still have to demonstrate that the proposed project would not be an unnecessary duplication of existing and approved services to be conforming with G.S. § 131E-183(6). Approval of this petition could have unintentional consequences on the current inventory of dialysis stations, complicating operations of the existing need methodologies.

BMA's Commitment to Staff Assisted HHD at Nursing Homes

BMA is willing and committed to working with nursing home providers to identify a solution that brings dialysis to where nursing home residents live. As stated in comments on previous petitions, BMA has already partnered with a nursing home in Alamance County and plans to begin offering home dialysis training and support services to the facility's residents later this year.

BMA is also currently in discussions with other nursing home providers throughout the state to provide staff assisted HHD for nursing home patients.

Conclusion

To be clear, BMA's concerns with Liberty's petitions is not competition. The patients that Liberty intends to offer dialysis treatment for are patients who are currently in an existing dialysis facility. Their safety and well-being is our utmost priority. BMA believes it would be to everyone's advantage to wait and see how a nursing home model operated under the standard methodology would feasibly work before approving more need determinations. While it is commendable that nursing home providers would like to eliminate the concerns of transporting nursing home patients off-site to dialysis three times a week, accomplishing that goal should not jeopardize patient safety and quality. **Perhaps the development of an interested party's workgroup working together on this should be the next step to avoid any unintended consequences by approving the need determinations that Liberty has requested.**

For the reasons discussed above, BMA and its affiliates respectfully ask that the Acute Care Services Committee and the SHCC deny Liberty's 2023 Petition for a County Need Determination in Alamance, Bertie, Brunswick, Buncombe, Chatham, Columbus, Cumberland, Davie, Durham, Forsyth, Franklin, Halifax, Johnston, Lee, Mecklenburg, Moore, New Hanover, Orange, Person, Robeson, Rowan, Sampson, Wake and Watauga Counties in the 2024 State Medical Facilities Plan.

Respectfully,



Fatimah Wilson
Director, Certificate of Need