

March 15, 2023

Ms. Micheala Mitchell, Chief Healthcare Planning & Certificate of Need
Dr. Andrea Emmanuel, Interim Assistant Chief Healthcare Planning
Dr. Sandra Greene, Chair, SHCC & Acute Care Services Committee
Ms. Elizabeth Brown, Planner
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Liberty Healthcare & Rehabilitation Services – Petition for Addition of Policy ESRD-4 in the 2024 SMFP

Ms. Mitchell, Dr. Emmanuel, Dr. Greene and Ms. Brown:

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), owns, operates and/or manages over 100 existing and or approved North Carolina dialysis facilities and provides in-center hemodialysis (ICHD) 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.

Fresenius Medical Care incorporates a Quality Improvement Program into each of its facilities and monitors patient outcomes on a regular basis. Quality is a primary concern for every Fresenius related facility across the state from the upper echelons of corporate leadership to the individual RN working at the patient chairside. Fresenius Medical Care, encourages all Fresenius related facilities to provide excellent care for every patient every treatment.

Liberty Healthcare & Rehabilitation Services (Liberty) has submitted a petition request for the addition of Policy ESRD-4 in the 2024 SMFP, which will allow for the development or expansion of a kidney disease treatment center in skilled nursing facilities statewide. Liberty's petition is problematic for a number of reasons, which will be discussed throughout these comments.

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.

On page 1 of the petition, Liberty states the following:

“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 Medical Advantage HMO insurance plan, and McNeill’s Pharmacy.”

It is clear that Liberty has an extensive history of offering many different healthcare services; however, dialysis is not one of them. Dialysis treatment is specialized care that requires specialized dialysis providers because of the acuity level of the patients being served. For this reason, dialysis providers are certified to offer dialysis services to ensure that the highest quality of care is being provided to the patient. While non-dialysis providers can be trained to monitor a dialysis patient undergoing treatment, it is not the same level of care as being treated by qualified professionals who specialize in dialysis care.

On page 2 of the petition, Liberty states the following:

“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.”

Nursing Home providers have no experience in providing dialysis services, particularly to patients who are very fragile and have a multitude of health problems. While it is true that this segment of the population has special healthcare needs that can be better addressed, allowing non-dialysis providers an opportunity to treat these patients in an outpatient setting to limit scheduling conflicts and transportation restrictions is not the solution. Certified dialysis providers are highly trained professionals, exclusively in the area of ESRD, which allows dialysis providers the ability to provide services safely all while monitoring clinical outcomes and improving patient satisfaction. While nursing home providers are skilled in providing services to exclusively to nursing home patients, they are inexperienced and lack the expertise needed to provide high quality dialysis care.

On page 3 of the petition, Liberty states the following:

“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 Certification 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)."

While Liberty's petition acknowledges the opportunity, a provider has to submit petitions to the Acute Care Services Committee and the State Health Coordinating Council (SHCC), it is clear that they do not want to undergo the yearly process that is currently in place to do so.

The petitioner provides no quantifiable data on a county, regional or statewide basis to support the need for outpatient dialysis stations at nursing homes. The SHCC and the Agency undergo a year long process of reviewing population data, facility census statistics, county use rates, etc. before making decisions on need determinations for healthcare services across the state. While it has been made abundantly clear that ESRD patients in nursing homes have specific challenges that can be better addressed, the petitioner has offered no information for the Acute Care Services Committee, the SHCC, or the Agency to considered to support that the best way to address the needs of ESRD patients in nursing homes is by the addition of Policy ESRD-4.

The statements in this section of Liberty's petition are conflicting in that on one hand, it addresses the specific needs of the nursing home ESRD patient population, but on the other hand, it states how Liberty and other nursing home providers should have the opportunity to offer these services at their facilities. Nursing home patients have a gamut of healthcare needs, including but not limited to physical therapy, occupational therapy, speech therapy, etc. All of these services require treatment by trained professionals who are experienced in these areas to ensure patient safety, patient satisfaction and improved clinical outcomes. Nursing home providers are not trained or experienced in dialysis services, thus outpatient dialysis providers should always be preferred provider for dialysis services.

In 2022, the Acute Care Services Committee and ultimately the SHCC, approved an adjusted need determination for six outpatient dialysis stations in Mecklenburg County. That need determination included specific language that stated,

"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." Thus, Liberty's assertions that a county need determination which would allow outpatient dialysis providers to apply for a Certificate of Need would "defeat

the purpose of this Petition's goal of providing a more patient-centered dialysis experience in the safest, least disruptive environment", has no basis because the SHCC has the authority to implement language in the need determination that any and all potential CON applicants must adhere to and, this language would be upheld by the CON Section reviewing the CON applications.

Any future county need determinations for outpatient dialysis stations approved by the SHCC would potentially include the same language as the need determination referenced above.

Lastly, Liberty's assertions regarding how an outpatient dialysis provider offers home dialysis to nursing home patients are misleading in that offering home dialysis is somehow taking services away from community-based dialysis services, which is simply untrue. Outpatient dialysis facilities are required to have back-up stations in the event of technical issues with equipment, thus outpatient facilities are equipped with backup stations that are in storage to ensure that services will continue to be offered in the event of technical difficulties.

On page 5 of the petition, Liberty states the following:

"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. ..."

Liberty's statements in its own petition suggest that it is Liberty who wants to avoid competition. Otherwise, Liberty would continue to submit a petition for an adjusted need determination for dialysis stations at a nursing home on a county basis, as was done in the summer of 2022. However, doing so would allow outpatient dialysis providers an opportunity to file a CON application to develop these stations, which is clearly something Liberty is attempting to avoid. Approval of Liberty's petition would eliminate competition between nursing home and outpatient dialysis providers for dialysis stations, particularly if the language of the policy is similar to the language of Policy ESRD-3, which is the basis for the proposed Policy ESRD-4 language that Liberty has offered in its petition. The language Liberty proposes, which it acknowledges is based mostly on the language of Policy ESRD-3 states in part that, *"licensed nursing homes may apply pursuant to this policy."* Outpatient dialysis providers are not licensed nursing home operators, and would not be able to apply pursuant to this proposed policy, which eliminates any competition to the nursing home provider.

On page 6 of the petition, Liberty states the following:

"Liberty plans to ensure the highest quality of care is being provided to nursing home ESRD patients using leading edge technology."

Chapter 1 of the SMFP outlines the first basic principle which guides the development of the SMFP. This principle encompasses safety, clinical outcomes and patient satisfaction, with an emphasis on safety. While technology is very important in offering dialysis care,

technology alone does not take the place of staff who are highly trained and qualified to provide dialysis care. Experienced dialysis providers are required to adhere to CMS Guidelines for operating a dialysis facility which include qualified staffing, medical oversight and professional development opportunities. While Liberty's petition mentions recent nationwide staffing shortages in the healthcare industry, it fails to address how as an experienced long-term care provider not already offering dialysis services, it will be able to recruit the qualified staff needed to safely offer dialysis services. Even CMS recognizes that a nursing home provider is not equipped to offer dialysis services without the oversight of an experienced ESRD provider, and as a condition of participation, CMS Guidelines would still require Liberty to enter into a written agreement with a dialysis facility.

On page 8 of the petition, Liberty states the following:

“Accordingly, Liberty has had discussions with providers and were, disappointingly, offered terms that are not economically viable and even financially exploitative.”

Liberty states that terms discussed with existing dialysis providers were not economically viable and financially exploitative, however the committee has no way to make an objective determination as to the accuracy of Liberty's statement above. Liberty provided no information for the committee to consider to determine whether or not it is more economically viable for Liberty to contract with an existing dialysis facility to provide services or to offer the services themselves. FMC and its affiliates have always been open to collaborating with other healthcare providers to ensure that dialysis care is safely and effectively being provided to dialysis patients. As evidence of this, FMC and its affiliates have partnered with a nursing facility in Alamance County and has been CON approved to begin offering home dialysis training and support services to residents of the nursing facility later this year. FMC and its affiliates will continue to welcome any opportunity to collaborate with another healthcare provider to offer home dialysis services, including to patients residing in nursing home facilities.

Conclusion

For the reasons discussed above, BMA and its affiliates respectfully ask that the Acute Care Services Committee and the SHCC deny Liberty's Petition for addition of Policy ESRD-4 in the 2024 SMFP

Respectfully,



Fatimah Wilson
Director, Certificate of Need