

August 10, 2022

Ms. Micheala Mitchell, Chief Healthcare Planning & Certificate of Need
Dr. Amy Craddock, 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 an Adjusted Need Determination for a Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 State Medical Facilities Plan

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

The following comments are submitted on behalf of the Fresenius Medical Care (FMC) affiliated dialysis facilities in North Carolina. FMC, through its affiliates, manages over 100 dialysis facilities in North Carolina and provides in-center hemodialysis (ICHD) as well as training and support for home hemodialysis (HHD) and peritoneal dialysis (PD) modalities.

Liberty Healthcare & Rehabilitation Services (Liberty) has submitted a petition request for the addition of an adjusted need determination for a nursing home dialysis pilot demonstration project in Mecklenburg County. The Liberty petition would allow for a six (6) station need determination to be added to Chapter 9 Table 9D: Dialysis Station Need Determination by Facility in the proposed 2023 State Medical Facilities Plan (2023 SMFP) at the Royal Park of Matthews nursing facility in Mecklenburg County. It is our belief that Liberty's petition has a number of issues, which will be discussed throughout these comments.

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

“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 needs [needs] plan healthcare insurance company and the original 145-year old retail 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 3 of the petition, Liberty states the following.

“Royal Park of Matthews has the necessary infrastructure to house outpatient dialysis stations, and therefore would requests a waiver of the SMFP requirement that a new dialysis facility have at least 10 stations. We believe that requirement was based on the presumed size (i.e., number of dialysis stations) needed to make a new ESRD center viable, a concern not present in the proposed demonstration project which would be housed in an existing, viable skilled nursing facility.”

The Basic Principles for End-Stage Renal Disease (ESRD) Facilities are outlined in Chapter 9 of the Proposed 2023 SMFP. Specifically, Basic Principle number one states,

“New facilities must have a projected need for at least 10 stations to be cost effective and to assure quality of care [emphasis added].”

While Liberty’s petition does mention that operating fewer than 10-stations would still be financially viable as a result of being located in an existing nursing facility, it does not address the quality of care issues that are associated with operating fewer than 10-stations. The basic principle referenced above was formed to ensure that new facilities would have enough patients to provide quality services and be financially viable.¹ Requesting a waiver of this principle would not be in the best interest of ESRD patients and would not help to ensure that all dialysis providers in North Carolina are providing quality of care.

Operating fewer than 10-stations is not ideal and has only been approved under special circumstances, for example, being located in rural and small communities. Royal Park of Matthews is located in Matthews, North Carolina, in Mecklenburg County. According to 2020 data from the North Carolina Office of State Budget and Management (NCOSBM), Mecklenburg County is the 2nd most populated county in North Carolina and Matthews is considered a suburb of Charlotte, North Carolina. According to the 2020 American Community Survey, Charlotte, is North Carolina’s most populated city and is not considered rural or small. Liberty has provided no other information in its petition for

¹ Acute Care Services Committee Agency Report, Adjusted Need Determination Petition for Outpatient Dialysis Stations in Orange County for the Proposed 2020 SMFP, September 17, 2019, p. 2.

the committee to consider as to 1) how it will ensure quality of care for the dialysis patients it is proposing to offer services on less than 10-stations and 2) why it is necessary to operate a facility with fewer than 10-stations in the 2nd most populated county in the largest city in the state.

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

“In response to a petition from Liberty on behalf of Royal Park of Matthews, the State Health Coordinating Council approved an adjusted need determination for six dialysis stations in Mecklenburg County to be included in a demonstration nursing home-only dialysis facility. This is a nursing home dialysis demonstration pilot project that is in the inventory but is not included in need determination calculations.”

Liberty’s petition does not discuss what unique circumstances specifically exist at the Royal Park of Matthews nursing facility that warrants this demonstration project. Liberty does not identify the number of dialysis patients currently residing at the facility to explain how it was determined that six stations would be sufficient for the proposed demonstration project. Further, Liberty is again requesting to be excluded from requirements that currently all existing dialysis providers must follow. Without any discussion regarding any unique circumstances at Royal Park of Matthews, the committee has no way to evaluate the reasonableness of Liberty’s request for the proposed demonstration project at Royal Park of Matthews, the number of stations being requested and why Liberty should be excluded from the required need determination calculations.

On page 4 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 proposed 2023 SMFP outlines the first basic principle which guides the developed of the SMFP. This principle encompasses safety, clinical outcomes and patient satisfaction, with an emphasis on safety². 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

² Proposed 2023 SMFP, Chapter One Basic Principles Governing the Development of this Plan, Page 2
<https://info.ncdhhs.gov/dhsr/ncsmfp/2023/02-2023PSMFP.pdf>

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 7 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 were, in fact, cost-prohibitive.”

Liberty states that terms discussed with existing dialysis providers were not economically viable and cost-prohibitive, 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.

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

“Currently, twenty-seven (27) of Liberty’s nursing home facilities have a least one dialysis resident, serving 80 total dialysis nursing home residents.”

Liberty acknowledges in its petition that 27 of its 37 nursing facilities have at least one dialysis resident. Liberty’s petition does not mention whether or not Royal Park of Matthews, the facility it is requesting to operate these six stations is one of the facilities that has a least one dialysis patient, yet its petition is requesting six outpatient dialysis stations. As previously mentioned, Liberty does not address how offering dialysis care to such a small number of patients will impact patient safety, quality of care, staffing, medical oversight and staff training.

On page 11 of the petition, Liberty states the following,

“The proposed pilot demonstration project will not result in unnecessary duplication of services. Instead, the proposed pilot demonstration project will serve to expand access to dialysis services for special nursing home patient populations that are otherwise underserved or served in suboptimal conditions and settings.”

Development of the SMFP is governed under the Certificate of Need law. **G.S. 131E-183(a)(6) of the CON Law** states,

“The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.”

Liberty states in the quote above that its petition is intended for the nursing home patient populations that are otherwise “underserved or served in suboptimal conditions”, thus approval of its petition would not result in the unnecessary duplication of dialysis services. However, the language that Liberty constructed above and is relying on (“underserved or served in suboptimal conditions”) is not the language stated in the CON Law referenced above. Liberty asserts that providing dialysis services to nursing home patients will not result in unnecessary duplication of existing or approved health service capabilities or facilities, however what Liberty is not taking into consideration is that all existing and approved dialysis providers who are or can be certified to provide home therapies already have the capability to provide dialysis services to patients residing in a nursing home.

As the committee is aware, there is a national emphasis on home therapies dialysis treatment, particularly since the signing of an Executive Order on Advancing American Kidney Health by former President Trump in 2019 that mandated that Secretary of Health and Human Services launch an awareness initiative at the Department of Health and Human Services to aid the Secretary’s efforts to educate patients and support programs that promote kidney disease awareness. As a result of that continued awareness, existing dialysis providers are experiencing significant growth in home therapy programs, growth that would include providing dialysis services to nursing home patients.

According to the ESRD Data by County Patient Origin Report for December 2021, a total of 2,810 home therapy patients (HHD and PD) or 14.6% of dialysis patients received their dialysis treatment by a home therapy modality (HHD or PD), this is an increase of 9.6% from December 31, 2019 (2019 is the year the Executive Order was signed). Clearly, the segment of the population that Liberty is intending to serve is already included in the patient population that existing dialysis providers are already serving and approving this petition would result in an unnecessary duplication of services already being provided.

Conclusion

For the reasons discussed above, FMC and its affiliates respectfully ask that the Acute Care Services Committee and the SHCC deny Liberty’s Petition for an Adjusted Need Determination for a Home Dialysis Pilot Demonstration Project in Mecklenburg County in the 2023 SMFP.

Respectfully,

Fatimah Wilson

Fatimah Wilson
Director, Certificate of Need