

March 16, 2022

Ms. Elizabeth Brown, Planner
Dr. Amy Craddock, Assistant Chief
Ms. Micheala Mitchell, Chief
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 ESRD Policy to the 2023 SMFP

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

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 a policy to be added to the 2023 State Medical Facilities Plan (SMFP), Policy ESRD-4, which would allow for the development or expansion of a kidney disease treatment center at a skilled nursing facility. The suggested petition is flawed for several reasons and will be discussed below.

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 2 of the petition, Liberty states the following,

“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 through the state, specifically in nursing homes, that necessitate the new End-Stage Renal Disease (“ESRD”) Policy proposed.”

The petitioner fails to demonstrate why the proposed policy is “necessitated” by “unique circumstances.” Outpatient dialysis providers also recognize that a nursing home can be a dialysis patient’s residence. The ability of outpatient dialysis providers to offer HHD or staff assisted HHD in a nursing home is a service that is already being provided. Specifically, in the last few months, both Fresenius and DaVita have been approved by the Agency to offer HHD in nursing homes in North Carolina in an effort to address the former President’s Executive Order to transform how kidney disease is prevented, diagnosed and treated. A new policy is not needed to do so.

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

“As will be discussed throughout this Petition, allowing for the development 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.”

Policy GEN-3: Basic Principles in the 2022 SMFP in its entirety states:

“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”

While Liberty discusses the safety and quality and equitable access components of Policy GEN-3 throughout this petition, it is important to note that Policy GEN-3 would not apply to a CON application filed by Liberty or any other provider pursuant to this policy because the policy is only applicable in a CON review when the application is being filed pursuant

to a need determination in the SMFP. Facility and county need methodologies for dialysis stations are treated as need determinations in the SMFP, thus a CON application being filed pursuant to a need determination would need to address Policy GEN-3. The petitioner is specifically requesting to be excluded from the need methodologies, however the result of that is Policy GEN-3 would not be applicable in a CON review.

On page 6 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.”

The petitioner provides no information or documentation in the petition to support its subjective assertions about terms offered by dialysis providers. The Agency has no way to make an objective determination as to the accuracy of Liberty’s statement above.

On pages 7-8 of the petition, Liberty states the following,

“This Policy would allow North Carolina to join Illinois at the forefront of providing dialysis services for this special nursing home patient population within the nursing home, which will directly correlate to an increase in home dialysis.”

The petitioner’s comment is unsupported. North Carolina and Illinois operate two separate and distinct CON programs based on the populations that they serve. The petitioner provides no evidence for why it is reasonable to adapt a home dialysis model from another state, with a different population demographic and under a completely different CON Law. The petitioner is also only relying on one source to conclude that Illinois CON Law allowing for nursing homes to offer dialysis services is the only reason for their home dialysis performance, without taking any other factors into consideration.

On page 10 of the petition, Liberty states the following,

“Liberty proposes to exclude existing and new 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. ...”

The petitioner’s comment fails to show that the proposed policy will not result in unnecessary duplication of services. **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.”

In addition, the population Liberty is proposing to serve under the proposed policy is already being served. As previously stated in these comments, Liberty has not addressed in this petition how the segment of the population it is proposing to serve under this policy is currently underserved. There are over 200 outpatient dialysis facilities in North Carolina that provide ICHD, HHD and PD that are already providing access to dialysis services, including care to those patients residing in a nursing home.

Conclusion

Liberty’s petition to add a policy allowing for the development or expansion of a kidney disease treatment center at a skilled nursing facility is flawed for all the reasons discussed above. Approval of this petition would be inconsistent with the CON Law in that it would not promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. It would also be an unnecessary duplication of existing or approved health service capabilities or facilities.

We strongly recommend denial of this petition.

Respectfully,



Fatimah Wilson
Director, Certificate of Need