
August 11, 2020

NC State Health Coordinating Council
Dr. Amy Craddock, Assistant Chief
Ms. Martha Frisone, Chief
Healthcare Planning and Certificate of Need Section
Division of Health Service Regulation
809 Ruggles Drive
Raleigh, North Carolina 27603

Re: Comments by Wake Forest Baptist Health regarding the Proposed 2021 SMFP,
dated April 5, 2020

Dear Members of the State Health Coordinating Council, Dr. Craddock and Ms. Frisone:

The following comments are submitted on behalf of the Fresenius Medical Care and its related dialysis facilities in North Carolina.

The comments by Wake Forest Baptist Health include the following statements:

“When the Agency allows the transfer of dialysis stations to the Home Only – Training Facilities it appears that the Agency is in direct violation of their own rules.”

*“The **uncontrolled movement of ICH stations creates a new less than 10 Station ICH facility...**”*

We disagree with both of the above characterizations.

First, dialysis stations relocated to a home only dialysis facility are dedicated exclusively to the provision of home hemodialysis training and support services. These stations are not utilized to provide back-up in-center dialysis treatments. Nor are these stations utilized for respite care. An applicant for a Certificate of Need, which is required in order to relocate the stations, must abide by the material representations of the CON application. Patients requiring back-up in-center treatment, or respite treatments, are referred to a nearby in-center dialysis facility.

Secondly, dialysis stations dedicated to home hemodialysis training and support are not moved without CON Agency approval. It is incorrect to suggest that dialysis stations are moved without appropriate regulatory oversight.

Development of dialysis stations at freestanding home dialysis programs is appropriate and consistent with contemporary standards of care. Further, these facilities comport

with the President's Executive Order on Advancing American Kidney Health (July 10, 2019). Since the Executive Order was issued, there has been an appropriate, and greater emphasis on home dialysis therapies. Growth of home dialysis is outpacing growth of the overall ESRD patient population.

Overall, the home patient population has increased at a greater rate than the ESRD patient population as a whole. And, within the home dialysis patient population, home hemodialysis has increased more rapidly than home peritoneal dialysis. The changes within the dialysis patient population and station utilization favor additional development of home hemodialysis stations within freestanding home dialysis training and support facilities.

We appreciate the opportunity to offer public comment on these matters, and look forward to the Staff and Committee recommendations.

Respectfully,

A handwritten signature in blue ink, appearing to read "Jim Swann", with a long horizontal stroke extending to the right.

Jim Swann
Director, Certificate of Need