

PUBLIC HEARING COMMENTS

REGARDING PETITION TO CHANGE THE ASSUMPTIONS OF THE NEED METHODOLOGY IN CHAPTER 9 OF THE 2024 SMFP

Presented by Fatimah Wilson, Director Certificate of Need

INTRODUCTION

Good morning/afternoon. Thank you for allowing me this opportunity to present oral remarks to you today. My name is Fatimah Wilson and I am here on behalf of Fresenius Medical Care Holdings, Inc. ("FMC") and its affiliates d/b/a Bio-Medical Applications of North Carolina, Inc. ("BMA"). Today, we are submitting a petition to the State Health Coordinating Council (SHCC) requesting a change to the need methodology in Chapter 9 of the 2024 State Medical Facilities Plan (2024 SMFP).

The proposed changes are requested to resolve ambiguity that resulted from changes in the 2022 SMFP, and to provide clarity on the development of new dialysis stations at home training facilities, which is not yet addressed in Chapter 9.

BACKGROUND

The term "home training facility" was first defined in the 2022 SMFP. A home training facility is an ESRD facility dedicated exclusively to the training of hemodialysis or peritoneal dialysis patients to dialyze at home or at a location other than a kidney disease treatment center that provides in-center dialysis. A "home patient" receives hemodialysis or peritoneal dialysis in the patient's home, except for training that is provided in an ESRD facility.

REASONS FOR THE PROPOSED ADJUSTMENT/CHANGE

Currently, the need methodology for dialysis stations includes only in-center dialysis patients, and specifically excludes all home dialysis patients. Furthermore, dialysis stations relocated from in-center facilities to home training facilities are excluded from the planning inventory.

There is no need methodology or need determination in the SMFP for dialysis stations in home training facilities, Chapter 9 does not address the development of new dialysis stations in home training facilities or the effect on the planning inventory and Policy ESRD-2 can only be used in limited circumstances where a provider already has in-center facilities nearby.

In addition, two recent CON reviews also illustrate the need for the changes requested in this petition. On September 15, 2022, FMS ENA Home, LLC (ENA Home), a subsidiary of BMA filed two CON Applications, Chowan Home Dialysis and Wilson Home Dialysis, each of which proposed to develop one dialysis station at an existing/approved home training facility to be used exclusively for home hemodialysis training and support services. BMA was not proposing to offer in-center dialysis services in either CON application.

To BMA's knowledge, the Chowan and Wilson Home Dialysis applications were the first applications to develop new dialysis stations in a home training facility in a service area without a need determination since the 2022 SMFP changes regarding home training facilities. Accordingly, both applications explained BMA's belief that a need determination in the SMFP was unnecessary.

While the Agency concluded that ENA Home demonstrated the need for the services proposed, both applications were denied, for the sole reason that the 2022 SMFP contained no need determination for dialysis stations in the service area. The Agency Findings for both applications stated,

“An alternative method or policy for developing new dialysis stations that would be used exclusively for home hemodialysis training, and that would not require a need determination in the SMFP would need to be developed and approved by the State Health Coordinating Council.”

CONCLUSION

To conclude, the petitioner will be submitting a petition in response to the Agency's decisions on the Chowan and Wilson Home CON applications and for the other reasons outlined above in these remarks. BMA is respectfully requesting clarification of the need methodology in Chapter 9 in that a need determination, which is based only on the in-center patient population, is limited to in-center dialysis stations. By doing so, dialysis providers will be able to ensure adequate access to home hemodialysis training and support services for the patients choosing the modality across the state.