Acute Care Services Committee Agency Report Petition to Establish a Need Determination Methodology for For Home Hemodialysis Training Stations

Petitioner:

Wake Forest Baptist Health

Contact:

Marshia Coe, RN, BSN, MSHA, COO, Health Systems Management, Inc. P.O. Box 7710 Tifton, GA 31793-7710 (336) 748-0575 <u>mcoe@wfopd.com</u>

Request:

Wake Forest Baptist Health requests to establish a need determination methodology for home hemodialysis training stations for outpatient in-center dialysis facilities in the *North Carolina 2021 State Medical Facilities Plan (SMFP)*.

Background Information:

Chapter Two of the *North Carolina 2020 State Medical Facilities Plan* provides that "[a]nyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections." The annual planning process and timeline allow for submission of petitions for changes to policies and methodologies in the spring.

ESRD services have two methodologies: the county need methodology projects need for the county; the facility need methodology projects need for a specific facility. When a county need determination exists, any qualified applicant may apply to add stations in an existing facility or apply to develop a new facility. When a facility need determination exists, only the facility that generated the need may apply to add stations.

ESRD providers report data annually for each certified dialysis facility on the current number of certified dialysis stations and the number of patients served. All certified dialysis stations are counted in the methodology, even though some may have been used for home training at the time the annual report was submitted.

The Centers for Medicare and Medicaid Services (CMS) defines a dialysis station as "an individual patient treatment area that provides sufficient space to accommodate the dialysis equipment and supplies needed for routine care and any emergency care indicated. There must be sufficient separation from other dialysis stations to afford protection from cross-contamination with bloodborne pathogens." In addition to these requirements, home hemodialysis training stations must also provide for patient privacy. However, CMS does not include regulations to certify stations specifically for home hemodialysis training.

Dialysis facilities must receive approval from Certificate of Need and Acute and Home Care Licensure and Certification Section to provide home hemodialysis training and support services. Approved programs provide training to the patient and their care partner, along with ongoing support and monitoring of the patient and care partner.

Analysis/Implications:

The Petition requests to establish a "new" methodology to provide in-center dialysis facilities with home hemodialysis training stations dedicated to training patients on a full-time basis.

It is the Agency's position that the proposed methodology pertaining to the need for "dedicated" home hemodialysis training stations cannot be implemented, given that CMS does not designate certified dialysis stations by task (i.e., in-center versus home training). When an in-center home hemodialysis station is not being used to train a new home hemodialysis patient it may be used for an in-center hemodialysis patient.

The Petition states that there exists "an unfair advantage for providers proposing home hemodialysis training in home-training-only facilities versus providers offering home hemodialysis training at in-center hemodialysis facilities." It is true that stations used for home hemodialysis training are likely to have lower utilization than other stations. The Agency has not found a disproportionate advantage given to any dialysis provider, nor did the Petitioner provide any evidence of such an advantage. ESRD providers are free apply to develop a home-training-only facility so that they do not have to use in-center stations for home training.

Agency Recommendation:

The Agency supports the standard methodologies for ESRD facilities. The Petitioner requests a methodology that simply cannot be implemented, based on how CMS certifies dialysis stations. Given available information and comments submitted by the March 18, 2020 deadline, and in consideration of factors discussed above, the Agency recommends denial of the Petition.