October 2, 2020

The Honorable Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Attention: CMS–1734-P , P.O. Box 8016

Baltimore, MD 21244–8016

**RE:  CMS-1734-P, CPT Code 49436**

Dear Administrator Verma:

On July 10, 2019 President Trump signed the Executive order that launched the Advancing America Kidney Health, a bold initiative designed to improve the lives of Americans suffering from chronic kidney disease (CKD) by reducing the incidence of End Stage Kidney Disease, improving treatment options for dialysis, and increasing the availability of organs for kidney transplantation. One of the specific goals of the initiative is for 80 percent of incident dialysis patients to begin dialysis on a home modality or with a transplant by the end of 2025. To achieve this, expanding both peritoneal dialysis (PD) and home hemodialysis (HHD) will be required.

Embedded PD catheters provide the potential advantage of placing the catheter in advance of need after a CKD patient has determined to choose PD as their preferred dialysis option. The PD catheter is then left in place until the patient needs to begin dialysis, at which time the catheter can be exteriorized for the patient to begin PD training immediately. The embedded catheter is an excellent strategy for increasing the number of incident PD patients starting on PD because patients remain committed to their modality choice once the catheter is in place. Furthermore, many advanced CKD patients experience unexpected sudden reduction in kidney function that results in urgent dialysis initiation with a central venous catheter. Placement of an embedded PD catheter in advanced CKD patients removes the need for timing of PD catheter placement relative to the initiation of dialysis. The benefits of embedded PD catheters have become much more relevant during the COVID-19 pandemic, when the dialysis community experienced difficulties with placement of PD catheters. This was despite CMS clarifying that AV access and PD catheter placement were essential procedures. We believe embedding the PD catheter ahead of time during a more favorable period would help many more patients initiate on PD during a pandemic.

At the present time, there is no reimbursement to cover the resources utilized when the externalization procedure is conducted outside of the hospital or ambulatory surgical center. We believe Nephrologists will refer patients for embedded catheters more often if they can be reimbursed for externalizing the catheters in their clinics. I support the increased utilization of the embedded catheter strategy by obtaining a non-facility reimbursement for performing the externalization procedure in the clinic or vascular access center environment.

I appreciate the opportunity to provide my comments to CMS on this issue. Please do not hesitate to contact me at **dinesh.chatoth@fmc-na.com** if you have any questions

Sincerely

Dinesh Chatoth, MD

Associate Chief Medical Officer, Fresenius Kidney Care