

May 17, 2019

The Honorable Alex Azar  
Secretary  
US Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Dear Secretary Azar:

We, the undersigned groups, write to ask you to establish a transitional add-on payment for new devices to the end-stage renal disease prospective payment system (ESRD PPS) for calendar year 2020. This action is consistent with your work to modernize and promote innovation in the delivery of dialysis care to the over 511,000 Medicare beneficiaries with kidney failure.

Recent innovation in ESRD has been modest relative to other diseases, and with respect to medical device innovation, nearly absent. Medical device innovation can transform the standard of dialysis care and reduce costs to Medicare and the healthcare system overall. However, the ESRD PPS fails to adequately pay for innovative new medical devices, like expanded hemodialysis, which have a reasonable expectation to improve patient outcomes or promote alternative modalities, like home dialysis. We ask that you use your broad statutory authority to implement a non-budget neutral add-on payment adjustment for new medical devices under the ESRD PPS. An add-on payment policy for truly innovative devices strikes a balance between efficiency and promoting innovation.

We appreciate your commitment to improving the standard of care for dialysis patients by addressing this barrier to transformative innovative devices in the ESRD PPS. We encourage you to work with us to adopt a new device transitional add on payment for new devices in 2019 as part of the 2020 rulemaking cycle.

Sincerely,

American Society of Nephrology  
Baxter Healthcare Corporation  
Home Dialyzors United  
Renal Physicians Association

American Society of Pediatric Nephrology  
Dialysis Patient Citizens  
National Kidney Foundation  
The Kidney Project (UCSF)