



March 17, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Protecting Access to Innovation in the Medicare End Stage Renal Disease Program

On behalf of Kidney Care Partners (KCP) and the patients we serve, I want to thank the Centers for Medicare & Medicaid Services (CMS) for the renewed commitment it has made to individuals living with kidney disease and kidney failure through its efforts in the Innovation Center with the new payment models and during the pandemic through the various policy waivers and flexibilities that supported the community during such a difficult time. As America shifts toward COVID-19 as endemic disease to be managed, it is time to review the Medicare End Stage Renal Disease (ESRD) Prospective Payment System (PPS) particularly in terms of creating a pathway for long-term adoption of innovative products and addressing the unprecedented workforce issues confronting the community.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

KCP requests that CMS, as part of the Calendar Year 2023 (CY 2023) proposed rule, address and seek comment on policies to ensure that the ESRD PPS provides sufficient funding to support the long-term adoption of new, innovative drugs and biologicals that CMS determines to be within existing functional categories. We also ask that CMS provide options for the base rate to reflect changes in the labor costs that the current market basket and proxies do not adequately address.

I. Seeking comments on policy to support long-term adoption of new innovative drugs and biologicals that may fall within existing functional categories.

The Medicare program, which provides coverage for nearly 80 percent of individuals whose CKD has progress to ESRD, needs to support innovation for individuals living with kidney failure who receive dialysis. Individuals living with kidney disease have experienced fewer innovative treatment options that may improve patient outcomes and reduce hospitalizations than individuals living with other chronic diseases. This lack of

treatment innovation creates a health disparity that disproportionately affects people of color. The Transitional Drug Add-on Payment Adjustment (TDAPA) is an important first step, but alone will not provide sufficient support for the long-term adoption of innovation or inspire innovators to develop new treatments for people who require dialysis. KCP recommends that CMS adopt a policy that assesses innovative products/treatment options based on information from the TDAPA period to add new money incrementally to the ESRD PPS after the TDAPA period to support the long-term adoption of the innovation.

It is important that the CY 2023 proposed rule signal that Medicare will support the long-term adoption of innovative drugs or biologicals, even those CMS determines to be in existing functional categories. Without this clarity, the “no new money” policy of today makes it difficult for dialysis facilities and nephrologists to adopt new innovation. Dialysis providers and nephrologists have clearly indicated that a blanket post-TDAPA no new money policy will mean that they will be less likely to provide the new, innovative products to patients even during the TDAPA period if they know that the existing PPS rate does not cover the cost of providing the product in the long-term and there is no offset in other costs. It also makes the area of dialysis care a less attractive one for companies in which to innovate, especially when compared to other healthcare sectors. The continuation of an automatic “no new money” policy for functional category drugs, coupled with the broad functional category definitions, creates a substantial barrier to innovation and ultimately to patient access to innovative products.

Ideally, CMS would retire the functional categories and evaluate all drugs and biologicals based on the products in the bundle at the time a new product is approved by the FDA. Alternatively, CMS could modify the post-TDAPA policy for drugs and biologicals to allow for new money to be added incrementally to the ESRD PPS when a functional category product is added to the bundle.

With a new product receiving TDAPA in April 2022 and other potential products applying for TDAPA in 2022, there is an urgent need to address this problem. CMS should seek comments on policy options during the CY 2023 rulemaking cycle and signal its decision to assess the adequacy of the base rate when new innovative products are added to the bundle post-TDAPA, even if those products come within existing functional categories.

Ideally, CMS would finalize a post-TDAPA policy that would assess a TDAPA functional category product based on data collected during TDAPA to determine if there should be an incremental increase to the ESRD PPS rate based on the utilization and price of the product compared to the existing funding in the base rate for such a product.

If CMS determines a product is within a functional category and awards it TDAPA, CMS would indicate at the time TDAPA is awarded that it will collect cost and utilization data, as well as any other information it plans to monitor, related to the product.

Before the product is added to the bundle and before the end of the TDAPA period, CMS would compare the cost and utilization of the new product to money already in the ESRD PPS for product(s) within the functional category that the new product would replace. If the new product's cost exceeds what is in the PPS rate, CMS would increase the rate by the amount the new product exceeds what is already in the PPS. If the new product's cost equals or is less than what is in the PPS rate, CMS would not adjust the PPS rate.

CMS could also assess whether the "average" individual receiving dialysis would receive the product based on TDAPA utilization. If the answer is "yes," the money would be added to the base rate and spread across all treatments. If the answer is "no," CMS would apply the special rule for low-volume products.

CMS could adopt a special "money follow the patient" rule for low-volume products to protect patient access and eliminate the disincentive created by allocating the new money across all patients rather than those for whom the product is used. Under the special rule, CMS could create a unique "pool" or base rate that would follow those patients who require the product. The pool/new base rate would be adjusted using the appropriate proxy for the product and the ESRD market basket. CMS could reassess the pool/new base rate over time to address the price and potential expansion of utilization again to make sure that the payment system supports patient access to the product. As part of this process, CMS would work with the community on defining low-volume products.

KCP recognizes that this is only one potential approach to assessing new drugs or biologicals that qualify for TDAPA and that CMS determines are within an existing functional category. As noted, it is critically important to signal to dialysis providers and nephrologists that CMS will assess new products using data collected during the TDAPA period before the TDAPA period begins. Given the likelihood of this situation for new products that are scheduled to launch in the near future, we ask that CMS use the CY 2023 proposed rule to signal a willingness to assess the base rate to protect patient access to innovative drugs and biologicals, even if they are within an existing functional category.

II. Seeking comments on policy options to address labor costs not captured in the current market basket and proxies.

One consequence of the pandemic has been a serious workforce shortage, which has resulted in an increased labor costs. *The Wall Street Journal* has reported that nursing salaries excluding bonus pay and overtime grew four percent in 2021.¹ This analysis does not account for the continued exponential growth seen in early 2022, nor the geographic variation that have driven costs significantly higher than the four percent reported. The study also does not include other health care professionals and technicians. MedPAC

¹Kelly Gooch. "Nursing Salary Grew 4% in 2021." *Becker's Hospital Review*. <https://www.beckershospitalreview.com/compensation-issues/nursing-salary-grew-4-in-2021.html> (Nov. 17, 2021).

continues to find that the Medicare margins for dialysis facilities are extremely narrow. In the 2022 *Report to the Congress*, MedPAC indicated that the margins for CY 2022 are 1.8 percent. Given these narrow margins, the rates do not provide sufficient resources to address a problem of this magnitude.

Dialysis facilities are struggling to remain competitive in attracting and retaining health care staff. Unlike other facilities, such as hospitals, dialysis facilities' payer mix is dominated by Medicare and Medicaid. These programs do not react as quickly to significant market changes and do not allow dialysis facilities to pass the increased costs along to the consumer as other sectors experiencing increasing labor costs have been able to do. KCP members report having to compete with retail companies for workers. These companies can increase the cost of their products to adjust to the higher wages. Facilities often lose their workers in these situations because retailers provide of higher wages, less stressful working conditions, and fewer hours. While the staff caring for individuals with kidney failure have risen to the challenge the pandemic presented, many are now burnt out and looking for different options, as so many other Americans are as well.

The current labor-related share of 52.3 percent of overall ESRD-PPS costs is based on the 2016 cost reports. However, changing that percentage will not address the problem at hand because shifting the percentage is done in a budget neutral manner in the short run, assigning higher payments to higher wage index facilities and lower payments to lower wage index facilities. In addition, the other half of the ESRD market basket – supplies and equipment – have also seen exponential increases in costs during the pandemic.

Therefore, KCP asks that CMS consider a COVID-19 specific labor adjustment to capture the unprecedented labor cost increases in 2021 and 2022.

III. Conclusion

Thank you for considering our suggestions. We are looking forward to meeting with you to discuss patient access to innovative products and address the serious workforce issues. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester at 202-534-1773 or klester@lesterhealthlaw.com, if you have questions or would like to discuss our comments.

Sincerely,



John Butler
Chairman

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Pediatric Nephrology
American Society of Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Healthcare Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma