



August 11, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue Southwest  
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

As the oldest and largest kidney patient organization in the United States, the American Association of Kidney Patients (AAKP) would like to extend our sincere congratulations on your historic confirmation as Administrator of the Centers for Medicare and Medicaid Services (CMS). We have followed your appointment, confirmation, and early tenure quite closely and we are highly pleased with your consistent commitment to elevating the health concerns of underserved populations and your focus on improved health outcomes for all Americans, especially among communities that are most vulnerable to chronic diseases, such as kidney disease and kidney failure.

AAKP has been closely aligned with CMS, as a strategic stakeholder and partner, since the 1973 authorization of the End Stage Renal Disease (ESRD) program. We serve the larger kidney community and multiple federal agencies as the leading patient-lead voice of kidney dialysis, kidney transplant, and chronic kidney disease patients and their families. AAKP has a productive history of collaboration and engagement with the U.S. Department of Health and Human Services (HHS) and CMS on issues related to care quality measurement, expansion of patient consumer access to new treatments, payment for new or emerging innovations designed to extend and improve the lives of kidney patients, as well as the importance of continuity of care and access to current treatments that a patient, along with their healthcare team, have found successful in their individual care regimen. As a *fully independent* patient organization, we carefully analyze issues based on our underlying principles and potential implications for both patients and taxpayers. We then raise our concerns as patients directly, and constructively, to HHS and CMS, unencumbered by the artificial constraints and special interest pressures that often accompany membership in larger multi-stakeholder umbrella coalitions. Over the past ten years, AAKP leaders have been trusted to objectively serve on, and/or co-chair, nearly a dozen CMS Technical Evaluation Panels related to kidney health. Further, AAKP leaders and patient advocates have conducted over a thousand Congressional, White House, and other Executive Branch engagements related to proposed CMS kidney policies and policy implementation to offer our objective, and largely supportive, patient insights and views on proposed patient reported outcomes.

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The Independent Voice of Kidney Patients Since 1969™

We believe the key to achieving more equitable healthcare rests upon the principle of patient consumer care choice, and, specifically, that kidney patients with coverage through CMS must have access to the same treatment options as any other American kidney patient. This includes both new innovations and established treatments, along with the requisite information they need to make informed care decisions in partnership with the medical professionals in whom they have invested their trust and confidence.

Over 400,000 Americans have End Stage Renal Disease (ESRD) and receive regular, lifesaving dialysis treatments. Most of these dialysis patients are covered by Medicare. Approximately 30 percent of all dialysis patients develop a condition in which their hormones are out of balance, called secondary hyperparathyroidism (SPHT). SPHT can cause bone disease and calcium to build up in tissues and organs such as the heart and blood vessels. African Americans with CKD have more severe secondary hyperparathyroidism than Whites. As you can see, a significant portion of the dialysis population.

As you know, in the ESRD Prospective Payment System (PPS), the initial mechanism for reimbursement of new drugs is the transitional add-on payment adjustment (TDAPA). Under current TDAPA guidelines, CMS only adjusts the base rate post-TDAPA if the new drug is outside a current functional category. Before this year, calcimimetics were billed separately, but starting in January of this year, Medicare added approximately \$10 to the bundled payment to cover the cost of all calcimimetic drugs so dialysis centers could continue to make them available to patients needing them. As you may be aware, the increased per-treatment bundled payment rate applies to all patients, regardless of whether they are receiving calcimimetics or not or which calcimimetic they receive (e.g. oral or intravenous), and was based on 18 months of utilization data for both oral and intravenous calcimimetic drugs.

**AAKP has been monitoring an alarming outgrowth of this policy, as manifested through provider implementation, that has been brought to our attention by concerned medical professionals and AAKP patient consumer members receiving CMS covered dialysis care. Instead of continuity of care for dialysis patients prescribed a treatment that has proven to stabilize their SPHT, we have learned that large and medium size dialysis providers are implementing new policies which send vulnerable patients through fail-first protocols (step therapy) giving them oral generic drugs first to see if the newer intravenous calcimimetic is needed, even when patients – prior to the bundle change – have already failed on the oral therapy or are intolerant to it.**

Furthermore, AAKP is aware that many dialysis centers' protocols have stopped allowing treatment with the intravenous drug until the patient's parathyroid hormone levels are upwards of 1,000 pg/mL which is well above the recommended guidelines of 600 pg/mL established by Kidney Disease Improving Global Outcomes (KDIGO) and the best advice of medical experts on the AAKP Medical Advisory Board (MAB). **Parathyroid levels greater than 600 pg/mL are associated with increased mortality.** This is a clear indication that many dialysis providers are implementing new protocols, many times unbeknownst to the patient and without concern for patient consumer choice, that are not aligned with clinical practice guidelines and that are detrimental to patient care by creating artificial barriers to treatment access and putting patients that are currently stable on an existing treatment at an increased risk of health complications or death for the ability to simply realize more savings within the adjusted bundle.

**AAKP believes this is a critical issue for kidney patients and an issue that has a disproportionate impact among underserved communities that are fully reliant upon CMS kidney care coverage and CMS protections. AAKP respectfully requests that CMS immediately investigate how this dialysis payment change is being implemented by dialysis providers to learn how it is impacting patients with the investigational goal of ensuring equitable access to the proper care for vulnerable ESRD patients.**

Thank you in advance for reviewing this urgent issue. AAKP is prepared to provide whatever assistance you need to advance this investigation on behalf of CMS covered kidney patient consumers. I can be contacted via Diana Clynes, AAKP Executive Director at (813) 400-2391 or [dclynes@aaqp.org](mailto:dclynes@aaqp.org).

Sincerely

A handwritten signature in cursive script that reads "Richard Knight".

Richard Knight  
President  
American Association of Kidney Patients  
*Former dialysis patient, current transplant recipient*

Cc:

Edward V. Hickey, III, USMC  
AAKP Vice President and Chair of Veterans Health Initiative  
Current chronic kidney disease patient

Paul T. Conway  
AAKP Chair of Policy and Global Affairs  
Former dialysis patient, current transplant recipient

Diana Clynes  
AAKP Executive Director