February 21, 2024

The Honorable Mike Johnson  
Speaker  
U.S. House of Representatives  
H-232, The Capitol Building  
Washington, DC 20515

The Honorable Hakeem S. Jeffries  
Minority Leader  
U.S. House of Representatives  
H-204, The Capitol Building  
Washington, D.C. 20515

The Honorable Steve Scalise  
Majority Leader, U.S. House of Representatives  
H-107, The Capitol Building  
Washington, DC 20515

Dear Speaker Mike Johnson, Minority Leader Hakeem Jeffries, Majority Leader Steve Scalise, and Members of the U.S. House Leadership:

My name is Edward V. Hickey, III, and I have the honor to serve as the President of the American Association of Kidney Patients (AAKP), the oldest and largest kidney patient organization in the nation. I am a service-disabled United States Marine Corps veteran, a kidney patient, and serve as the Chair of AAKP’s Veterans Health Initiative (VHI), the largest non-profit initiative engaging veterans in preventative kidney health and innovative treatments for kidney-related comorbidities.

I am writing today to express our deep concern regarding the ongoing negotiations around the government funding deadline scheduled for March 2024 and the implications on kidney care for the more than 37 million Americans living with kidney diseases.

On behalf of the AAKP, we are respectfully and specifically requesting the inclusion of date-change provisions to postpone the integration of oral-only phosphate lowering therapies (PLTs) into the End Stage Renal Disease (ESRD) payment bundle by one year. This action would extend the deadline to January 1, 2026, in Section 204 of the Stephen Beck Jr. Achieving a Better Life Experience (ABLE) Act of 2014.

Many Americans suffering from ESRD depend on PLTs to manage their phosphate levels. Patients with kidney failure often experience high levels of phosphate in their bloodstream which, if untreated, has been independently associated with an increased susceptibility to heart attacks or strokes. Nearly 80% of current dialysis patients rely on phosphate binders to eliminate excess phosphate from their
bodies. There are 550,000 patients undergoing dialysis in the United States, with an estimated 440,000 Americans currently relying on PLTs to effectively manage their health. PLTs must be taken with food, due to the fact that meals and snacks cannot be present or consumed during dialysis sessions or visits at dialysis centers, patients currently take these drugs at home with a meal or snack.

Patients have broad access to PLTs under Medicare Part D, but unless Congress acts, CMS has stated they will shift oral-only therapies, like PLTs, into the Part B ESRD Medicare Prospective Payment System (PPS or “bundle”) starting January 1, 2025. The planned CMS action comes at a time when the ESRD PPS bundled payment system is already strained. Due to the stress on the bundled payment system, kidney care treatment patterns are often dictated by rigid protocols that are not patient-centered and are, in many cases, counter-intuitive to the expert care nephrologists would prefer to tailor to individual patient needs. Further, PLTs present a complex challenge when managed through protocols, as many patients only respond to one specific drug or combination of drugs to achieve their clinical serum phosphorus level targets.

The Government Accountability Office’s (GAO) November 2023 report warns that integrating these drugs into the bundle would pose operational hurdles for all dialysis providers, potentially resulting in a reduced or delayed availability of PLT products for patients. Furthermore, the report highlights a concerning trend where doctors would resort to prescribing older, calcium-based generic drugs despite clinical treatment guidelines advocating for limiting the use of calcium-based phosphate binders.

AAKP believes that any attempt by CMS to wedge PLTs into the bundled payment system represents an unwarranted and misguided bureaucratic maneuver that will compromise the long-term health of American kidney patients. Further, AAKP believes this proposed CMS action is yet another example of a Government Determinant of Health (GDoH) that will disproportionately impact the most vulnerable Americans and lead to even higher unnecessary and avoidable costs to taxpayers when the health of ESRD kidney patients is jeopardized. A disproportionate number of individuals afflicted with ESRD are minorities and individuals who live in rural and low-income communities. Black, Hispanic, and Native Americans have significantly higher rates of ESRD and are also more inclined to opt for Medicare Advantage coverage.

If CMS moves forward with their plans to shift coverage of PLTs into the ESRD bundle, they will not only exacerbate historic health disparities among kidney patients, but the agency will also directly contradict and undermine the stated, bipartisan consensus for better kidney care outcomes emphasized under multiple Congresses. This bipartisan consensus for better kidney outcomes is also represented in the 2019 Executive Order on Advancing American Kidney Health signed by President Donald Trump and the multiple, stated commitments of President Joe Biden to improve kidney health within marginalized communities. AAKP believes Congress must intervene on this issue because, left unchecked, CMS will reverse long-held national kidney health goals autonomously and without accountability for the negative impacts on people.

AAKP is also concerned about how this planned CMS policy will also disproportionately affect the 48% of Medicare patients who have opted for Medicare Advantage. Unlike Traditional Medicare, Medicare Advantage plans are not obligated to provide an immediate, separate payment for these therapies in their agreements with dialysis providers. Historically, when the oral-only bundled drug policy was enacted and when the separate payment pathway was established within the ESRD PPS, Medicare
patients with ESRD were barred from enrolling in Medicare Advantage due to their condition. However, in 2021, a change in law has led to a rapid influx of ESRD patients into Medicare Advantage, expected to reach nearly 60% in the coming years. Consequently, there has been insufficient time to thoroughly examine or address appropriate reimbursement mechanisms for innovative drugs and biologics for this expanding segment of Medicare beneficiaries.

Congressional action has previously upheld accessible coverage for PLTs, and it is essential that Congress act again. We firmly believe the only long-term solution to minimize patient risk is the passage of H.R. 5074, the Kidney PATIENT Act of 2023. The Kidney PATIENT Act would instruct CMS to delay adding PLTs to the ESRD bundle until 2033 or until the Food and Drug Administration approves an intravenous treatment for lowering phosphate that can be delivered during a dialysis session. The Kidney PATIENT Act, along with the proposal for a one-year postponement in integrating oral-only PLTs into the ESRD payment bundle, has garnered support from 57 additional advocacy organizations. The complete list of endorsing organizations is in Appendix A.

**In the short-term, delaying the inclusion of oral-only PLTs in the ESRD bundle by one-year is a critical step to ensure patient safety and equitable access.**

Thank you for your dedication to this important issue. We appreciate your consideration in making this temporary delay a reality as we persist in championing the comprehensive solutions outlined in the Kidney PATIENT Act.

Sincerely,

EDWARD V. HICKEY, III  
President, American Association of Kidney Patients

Cc:

Paul T. Conway  
AAKP Chair, Policy & Global Affairs

Diana Clynes  
AAKP Executive Director

A: 14440 Bruce B. Downs Blvd  
Tampa, Florida 33613

T: 800-749-2257

F: 813-636-8122

W: www.aakp.org

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APPENDIX A

National and State organizations that have formally endorsed a Congressional one-year postponement in integrating oral-only PLTs into the ESRD payment bundle as well as the Kidney PATIENT Act, H.R. 5074

National Minority Quality Forum Action Network
A. Philip Randolph Institute
Advocates for Responsible Care
Alliance for Aging Research
American Association of Clinical Endocrinology
American Association of Kidney Patients
American Health Care Association
American Kidney Fund
American Society for Nephrology
American Society of Consultant Pharmacists’
Antioch South Baptist Church (Atlanta, GA) - Pastor Marvin Gordon, Senior Pastor
Arizona Blood Alliance
Arizona Chronic Care Together Coalition Atlanta
Black Nurses Association
Bethesda Baptist Church
Breaking the Sickle Cell Cycle Foundation
California Chronic Care Coalition
Calvary Temple Baptist Church (Atlanta, GA) - Pastor J. O. Jackson, Senior Pastor
Center for Patient Advocacy Leaders (CPALs)
Coalition for Cultural Change
Cornerstone Community Baptist Church (Atlanta, GA) - Pastor W. J. Lawson, Senior Pastor
Crown of Glory Baptist Church (Atlanta, GA) - Pastor Joshua McKinsey, Senior Pastor
Dialysis Patient Citizens
Eastern Shore of Maryland Sickle Cell Disease Association
Faith Advisory Council for Community Transformation
Fellowship Baptist Church - Pastor Stanley Smith, Senior Pastor
Gerontological Society of America
HEAL Collaborative Healthy Women’
iAdvocate
Kidney Care Partners
Kidney Care Partners of Central PA
Latino Connection
Looms for Lupus
Lupus and Allied Diseases Association, Inc.
MassBio
Millennium Man Ministries MTS Sickle Cell Foundation
National Association of Nutrition and Aging Services Programs National Center for Assisted Living
National Consumers League
National Grange
National Kidney Foundation
NewYorkBIO
New York State Osteopathic Medical Society
Northwest Kidney Council
Partnership to Fight Chronic Disease Redmoon Project
Renal Healthcare Association Renal Physicians Association Renal Support Network
RetireSafe
Ruby A. Neeson Diabetes Awareness Foundation
Rx in Reach Coalition
Sickle Cell/Thalassemia Patients Network Texas Kidney Foundation
Texas Renal Coalition
Washington State Academy of Nutrition and Dietetics