AAKP
American Association
of Kidney Patients
aakp.org

March 17, 2026

The Honorable Jason Smith
Chairman, Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

The Honorable Vern Buchanan
Chairman, Subcommittee on Health Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Re: Subcommittee on Health Hearing — Systemic Challenges Undermining Kidney Disease Care and Advancements in Prevention and Innovative Treatments (Wednesday, March 18, 2026, 2:00 PM, 1100 Longworth House Office Building)

Dear Chairman Smith and Chairman Buchanan:

On behalf of the American Association of Kidney Patients (AAKP), the nation's largest and oldest independent kidney patient organization, I appreciate the opportunity to comment on the systemic challenges undermining kidney disease care and how advancements in prevention and innovative treatments can improve outcomes and lower costs for patients, as the Subcommittee on Health prepares to examine these critical issues at its upcoming hearing. For our members and their families, including the great majority who participate in federal elections through our non-partisan KidneyVoter™ registration program, today's hearing is a historic milestone that will further increase the impact of the patient voice within the nation's kidney care system and we applaud you for your consistent efforts to advance patient-centered kidney care, especially among those living in rural areas and within underserved communities.

Since our founding in 1969, AAKP has advocated for expanded patient care choice, unfettered access to all safe, FDA-approved diagnostics, devices, and drugs, and federal policies that accelerate innovation and fully empower patients to live independently, maintain employment, and contribute to society. AAKP defines kidney disease as both a healthcare issue and a workforce issue. In the United States alone, an estimated 37 million people have chronic kidney disease (CKD), including 800,000 with kidney failure, whose kidney care costs the American taxpayer over $100 billion a year. Those costs do not include the additional expenses to the nation, and patients, stemming from labor force dropouts, disability and dependency caused by this chronic illness, and the massive burdens to both patients and taxpayers associated with obsolete, status quo technologies found in current kidney care.

AAKP has also, for the past twenty years, alongside our allied kidney stakeholders across the kidney community, called upon the U.S. Preventive Services Task Force (USPSTF) to step-up and make a recommendation for increased kidney disease screening and prevention as a strategic tool in the nation's efforts to prevent the progression of this horrible disease. AAKP considers the 20-year record of failure by USPSTF to take meaningful and substantive action on kidney disease a national embarrassment and significant setback for research, science, and clinical trials. Last year, AAKP took a leadership role within the kidney community by being the first to publicly call upon Health and Human Services Secretary Robert F. Kennedy, Jr. to dismiss the sitting members of the USPSTF, and in their place, consider the appointment of a more forward-thinking group of experts including kidney doctors, transplant surgeons, organ donors, and kidney patients whose insights would be better aligned to the national priority of defeating kidney disease.

I. The Scope of Kidney Disease and the Imperative for Transplantation

Chronic kidney disease affects approximately 37 million Americans, including more than 800,000 individuals living with end-stage kidney disease (ESKD). The only treatment for ESKD is renal replacement therapy such as kidney transplantation or maintenance dialysis therapy. The five-year survival rate among patients with ESKD remains dismally low, with roughly 60 percent dying within a five-year timeframe. According to 2020 data, 69 percent of patients with ESKD were on dialysis and 31 percent received a kidney transplant. Kidney transplantation remains the most effective treatment for ESKD, with substantially higher survival — approximately 80 percent at five years, compared with less than 50 percent in patients treated with dialysis alone. Congress, based on the Congressional debates in the early 1970's, initially envisioned dialysis services as a rehabilitative bridge for those awaiting transplant so that patients could return to their full-time or part-time jobs in the trades and professions. Medically, with increased time on dialysis, patients can experience increased sensitization, reduced transplant success, and worse overall outcomes including premature death.

The cost disparity between dialysis and transplantation is striking. In 2022, Medicare fee-for-service spending per person per year was over six times higher for patients on dialysis ($298,214) than for transplant recipients ($45,128). A probabilistic model of 10,000 potential transplant candidates predicts that kidney transplantation achieves an average incremental cost-effectiveness ratio of less than $50,000 per life-years saved, demonstrating that kidney transplantation is cost-effective compared with dialysis, regardless of age and comorbidity status. Yet in 2022, there were 131,194 newly registered ESKD patients, and only 29,064 were added to the transplant waitlist. Prioritizing transplantation — including increased patient opportunities for transplant access and improved patient readiness to receive a transplant — has been a consensus national priority for decades and served as a cornerstone of President Donald Trump's 2019 presidential Executive Order on *Advancing American Kidney Health*. AAKP was a very proud participant in the White House's stakeholder development of the Executive Order on *Advancing American Kidney Health* and has consistently fought to advance its goals of moving kidney disease prevention and early intervention further upstream, increasing the utilization rates for home dialysis and its embrace of new organ technologies – including artificial implantable and wearable kidneys and xenotransplantation, to address the nation's limited organ supply.

As a patient-led organization, we find it particularly appalling that, in this golden era of American medical innovation, a mortality rate of over 50 percent at five years for most dialysis patients is still considered acceptable among some medical providers, some career federal agency officials at the Centers for Medicare and Medicaid Services (CMS), and other so-called policy experts. In light of the significant, evidence-backed innovations that have entered the market aimed at strengthening kidney patient health, including preventing catheter-related blood stream infections (CRBSIs), improving hemodialysis access and quality, and advancing the nation's goals for transplant readiness and transplant opportunities – we know America can and must do better for patients and that increased Congressional oversight is strategically important to this mission.

II. Hyperphosphatemia: A Critical and Modifiable Barrier to Patient Health and Transplant Readiness

Among the myriad of complications facing patients with ESKD undergoing maintenance dialysis, hyperphosphatemia is a significant, independent, and modifiable predictor of mortality, carrying a 12 percent attributable mortality risk that increases death risk two- to six-fold higher than anemia, hypercalcemia, and hyperparathyroidism. Hyperphosphatemia promotes hypertension, atherosclerosis, left ventricular hypertrophy, and myocardial fibrosis, making it a major risk factor for cardiovascular mortality in CKD. Each one-mg/dL increase in serum phosphate has been associated with a roughly 23 percent increase in mortality risk among patients with CKD. Cardiovascular disease remains the leading cause of death among patients receiving maintenance dialysis, accounting for over half of all known-cause deaths.

The consequences of uncontrolled hyperphosphatemia extend directly to transplant readiness and long-term transplant outcomes. Elevated pre-transplant serum phosphate is associated with an increased risk of all-cause and cardiovascular mortality, transplant failure, and worse post-transplant outcomes, including higher risks of delayed graft function and graft loss. In one analysis of 801 patients on dialysis who received transplants, those in the highest quartile of pre-transplant phosphate levels had 1.7-fold higher odds of delayed graft function compared with those in the lowest quartile. In contrast, maintaining phosphate in the target range — for example, below 5.5 mg/dL — has been linked to improved graft survival rates. Many transplant centers consider uncontrolled hyperphosphatemia as part of the overall assessment of a dialysis patient's readiness for transplant. Poor phosphate control can indicate nonadherence to diet or phosphate binders and is often accompanied by uncontrolled hyperparathyroidism and vascular calcification — factors that could hinder transplant success.

Hyperphosphatemia may therefore limit access to, as well as success of, kidney transplantation. Despite clinical guideline recommendations for serum phosphate management, real-world data indicates that between 27 and 70 percent of patients are still unable to achieve or sustain target serum phosphate levels, even when dialysis, phosphate binders, and dietary modifications are used together. This long-standing challenge is partly attributable to the limitations of status quo phosphate binder therapies, including the extremely high pill burden in the setting of fluid restrictions and resultant poor adherence. For context, it is not unusual for kidney patients to take thousands of phosphate binders per year, in addition to their other medications, to try to maintain their phosphorous targets. This persistent gap between guideline recommendations and real-world phosphate control underscores the urgent need for individualized and more effective treatment strategies, including novel phosphate-lowering therapies.

III. Concerns with the 2024 Decision to Bundle Oral-Only Therapies

Against this clinical backdrop — where access to the full spectrum of phosphate-lowering therapies is essential for patient health, transplant readiness, and long-term cost savings — CMS's 2024 subjective policy decision to bundle oral-only therapies into the ESRD Prospective Payment System is particularly alarming. On January 1, 2025, CMS implemented the 2024 Biden Administration policy decision to shift all oral-only therapies, including phosphate-lowering therapies (PLTs), from Medicare Part D into the

ESRD PPS bundle under Part B. AAKP — alongside kidney professionals, other kidney stakeholder organizations, and the Government Accountability Office (GAO) — strongly opposed this change. AAKP publicly warned that bundling PLTs would restrict patient access, particularly for vulnerable patients in rural and low-income communities who cannot easily reach a dialysis facility. At its core, AAKP believes this CMS policy stands in complete contradiction to President Donald Trump's widely praised 2019 Executive Order on *Advancing American Kidney Health*, which emphasized improved kidney patient health outcomes, transplant readiness, and improved opportunities for transplantation.

Unfortunately, the practical impacts on both kidney patients and professionals since January 1, 2025, have confirmed our initial concerns. AAKP's Center for Patient Research and Education recently surveyed more than 500 kidney patients and clinicians to assess the consequences of this CMS policy implementation:

- 38 percent of patients reported disruptions in PLT access since January 1, 2025.
- 72 percent of kidney professionals reported similar disruptions in their ability to prescribe PLT medications to their patients since January 1, 2025.
- 96 percent of survey respondents agreed that patients, and the physicians they choose to treat them, should have access to all safe and FDA-approved medications that improve patient health and decrease the burdens associated with other or older types of treatments.

These findings confirm that bundling oral-only drugs has already undermined patient care and transplant readiness, and contradicted CMS's 2024 claim that this policy would expand patient access. Further, we believe the American taxpayer will bear even greater costs as negatively impacted patients become ill and less medically stable. A recent story in McKnight's Long-Term Care News chronicles the stories of vulnerable kidney patients in specialized nursing facilities, including nursing homes, who are not getting critical access to their PLT therapies.

IV. CMS's Budget Projections Underscore Reduced Access

In the 2025 ESRD PPS final rule, CMS projected that incorporating oral-only drugs would increase Medicare spending and improve access. By contrast, the July 2025 proposed rule now estimates PLT spending to be "more than 50 percent lower than projected" - $380 million in 2025 versus the previously projected $870 million. CMS offers zero explanation for this dramatic reduction, and we believe the agency's ongoing lack of transparency on the subject is indicative of the fact that CMS staff know there are serious problems with this policy. The most plausible interpretation of this budget data is that savings are being generated not from efficiency but from suppressed patient utilization – precisely what patient advocates and other stakeholders predicted in 2024.

AAKP asks the Subcommittee to monitor this growing situation closely, strongly encourage CMS Administrator Dr. Mehmet Oz to take immediate corrective action, and to hold career agency officials still defending this policy fully accountable for the barrier to PLT access they created and all resulting negative patient impacts.

V. Impact on Patient-Physician Decision-Making

The abrupt and unexplained decline in projected spending suggests that kidney patients, especially those facing socioeconomic barriers, are not receiving clinically appropriate PLT management. This outcome compromises and intrudes upon the patient-physician relationship by forcing practitioners to rely on older, less effective medications to remain within the PPS's constrained reimbursement. Under the bundled payment system, patient choice and access to new innovations is limited to the discretion of dialysis providers and their efforts to minimize costs instead of being determined by kidney doctors working to protect the best interests of their patients based on a patient's unique risk profile and vulnerabilities. When between 27 and 70 percent of patients already cannot achieve target phosphate levels with existing therapies, restricting access to the full range of phosphate lowering innovations — including novel therapies that may finally close this treatment gap — is a policy that directly harms patients, jeopardizes transplant readiness, and increases long-term costs to the American taxpayer.

VI. Transplant Readiness Requires Transparency and Transplant Opportunities

Evaluation of transplant readiness suffers from a lack of transparency. Clinical markers such as serum phosphate can be influenced by disparities in access to healthy foods and medical care. When these markers inform decisions about transplant readiness, there is a risk of further disadvantages to patients already burdened by structural inequities. In the context of ongoing organ shortages, clarifying how such variables are considered in transplant eligibility is essential to ensure equity, consistency, and accountability in the allocation of this life-saving resource. To better understand the impact of serum phosphate control on transplant access and equity, real-world tracking of transplant readiness metrics — including time-to-waitlisting, transplant rates, and post-transplant outcomes, stratified by serum phosphate levels and the types of phosphate-lowering therapies employed — is urgently needed. Such data will be instrumental in evaluating whether more aggressive and individualized phosphate management leads to earlier, more equitable transplantation decisions and, ultimately, better outcomes for patients and the healthcare system alike. In recognition of this serious problem, AAKP initiated National Phosphorus Awareness Day, recognized every April 5th, to raise awareness of the need for timely and uninterrupted treatments and proper phosphorus management.

VII. Additional Systemic Challenges: Infection Prevention and Transplant Drug Innovation

The systemic challenges undermining kidney disease care extend beyond PLT access. First, CMS's bundled payment system also stands in the way of patients having consistent, long-term access to new infection prevention innovations. Among hemodialysis patients covered by CMS/Medicare, catheter-related bloodstream infections (CRBSIs) harm 25,000 hemodialysis patients per year at a cost of over $2 billion to treat. These infections are life-threatening, impact patient readiness for a transplant, and disproportionately impact minority kidney patients. New infection prevention innovations that became available in 2024 have reduced these often deadly bloodstream infections by over 71 percent, but not all patients have access to this innovation.

Second, AAKP urges the Subcommittee to monitor FDA progress on adopting a new clinical endpoint that will measure long-term organ transplant survival and jumpstart the next generation of safer transplant drugs. Status quo immunosuppressive therapies are currently based on FDA drug approvals from over 20 years ago, with a clinical endpoint of one-year graft survival. Current transplant drugs can have severe long-term side effects, including gastrointestinal issues, toxicity to the transplanted organ, and cancer. The national goal is to transplant kidney patients once, help them avoid organ rejection, and avoid the need for patients to return to dialysis and the national organ waiting list. Congress should insist that FDA act with a sense of urgency and not wait another decade to jumpstart safer transplant drug development.

VIII. Recommended Actions

AAKP respectfully urges the Subcommittee to use its oversight authority to address these systemic challenges. To that end, AAKP recommends:

1. Restore PLTs and other oral-only therapies to Medicare Part D until such time that CMS staff can demonstrate, with transparent data, that bundling will not jeopardize ongoing kidney patient access or quality of care.
2. Publish a detailed explanation of the variance between original and current PLT spending estimates, including the data and assumptions underlying both sets of projections.
3. Engage directly with kidney patients, clinicians, and kidney advocacy groups to develop a more commonsense and sustainable payment policy that protects access to all FDA-approved treatment innovations.
4. Work with CMS and other relevant agencies to schedule public oversight hearings so that policymakers and stakeholders can fully examine the consequences of the 2024 Biden Administration policy decision and develop legislation that will better protect the interests of both patients and taxpayers.
5. Encourage Congress to work with patients, medical professionals, and innovation leaders to reimagine a more patient-centered approach to paying for new kidney innovations — including infection prevention technologies and novel phosphate-lowering therapies — while reducing long-term taxpayer costs.
6. Demand that FDA establish a clear decision timeline for approving a new clinical endpoint for transplant drugs that measures long-term outcomes beyond one-year graft survival.

A truly patient-centered payment model must reward innovation, reduce barriers to new care approaches and treatment options, and preserve the integrity of the physician-patient relationship that is central to high-quality care. We strongly encourage the Subcommittee to publicly explore all other instances where new, safe FDA-approved medical innovations designed to improve patient-defined quality of life and survival are being restricted by subjective CMS policy interpretations and decisions at the career staff level. AAKP stands ready to assist the Subcommittee in its efforts to shine additional light on this issue and bring the practices of the agency more in-line with federal policy goals articulated and advanced by President Trump and the appointed HHS and CMS leadership teams.

IX. Conclusion

Kidney disease imposes an enormous physical, emotional, and financial burden on millions of Americans — including American taxpayers. Ill-informed policy decisions that further restrict treatment options only compound these burdens and undermine the national consensus that better kidney health outcomes can and must be achieved. CMS can still mitigate the harm to patients caused by bundling oral-only therapies by promptly restoring PLTs to Medicare Part D, and Congress can play a vital role in ensuring that kidney patients have access to the innovations — from novel phosphate-lowering therapies to next-generation transplant drugs to infection prevention technologies — that will save lives, reduce costs, and promote health equity. Doing so will uphold the integrity of the patient-physician relationship and align federal policy with President Trump's kidney care priorities established in 2019.

We are grateful for the Subcommittee's attention to these critical issues and stand ready to serve as a resource for the Committee. Over the past decade, AAKP patient advocates have helped advance the passage of the bipartisan law modernizing the Organ Procurement and Transplantation Network via greater competition and oversight (2023); lifetime transplant drug coverage for kidney transplant recipients (2020); the presidential Executive Order on *Advancing American Kidney Health* (2019); new job protections for living organ donors under the Family Medical Leave Act via the U.S. Department of Labor (2018); and legislation allowing HIV-positive organ transplants for HIV-positive patients (2013). We look forward to continuing this work alongside Congress to improve the lives of kidney patients across America.

Thank you for considering the viewpoint of America's largest kidney patient organization. If you have questions or require additional information, please contact Diana Clynes, AAKP Executive Director, at (813) 400-2391 or dclynes@aakp.org.

Respectfully submitted,

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