NATIONAL FORUM
FOR HEART DISEASE & STROKE PREVENTION

Monday, August 17, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: [CMS-1848] Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz,

The National Forum for Heart Disease & Stroke Prevention (National Forum) appreciates the opportunity to comment on the updates made to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and how the updates may create unintended consequences resulting in barriers to patient access to evidence-based care that is appropriate for them. National Forum is a non-profit, non-partisan organization dedicated to empowering all people to attain optimal cardiovascular health and well-being throughout their lifespan. The National Forum is a coalition of patients, providers, public health, payers, purchasers, and innovators.

Phosphate-lowering therapies (PLTs), including phosphate binders, are a medical necessity to the 37 million Americans living with chronic kidney disease (CKD), including those with ESRD. As you know, both CKD and ESRD are contributing factors to cardiovascular disease (CVD), the primary cause of mortality in the United States.[1] Oral-only phosphate binders, often taken with meals, work to manage serum phosphate levels. Access to appropriate medications impacts adherence to phosphate binders that reduce the risk of cardiovascular mortality and increases likelihood of successful transplantation. Helping patients achieve adequate adherence to medications helps improve health

outcomes and allows people living with CKD/ESRD to continue to work and contribute to the economy.

A meta-analysis of randomized controlled trials consisting of 18,376 patients shows that phosphate binders are evidence-based solutions to reduce serum phosphate, [2] a key predictor of kidney transplantation readiness and post-transplant outcomes.[3] When access to the appropriate therapy is restricted, risk of negative health outcomes increases.

We acknowledge, in some instances, that payment bundling has improved access for those who were not previously beneficiaries under Medicare Part D; however, we know from results of previous bundle changes that bundling medications into the ESRD Prospective Payment System (PPS) has been proven to disrupt access to life-saving therapies and patient adherence to appropriate care.[4,5,6] The PPS bundle update made in 2011 negatively impacted patients' access to innovative medications.[4] In 2021, the PPS bundle update resulted in restricted access to effective medications due to the financial incentive created by a fixed payment. [5] In an American Association of Kidney Patients' Center for Patient Research and Education survey [6] both patients and providers reported disruptions to PLT access since the January 2025 update. CMS is aware of, *and has acknowledged*, that the bundled payment system created a financial incentive resulting in restricted access to innovative therapies for ESRD.[5] The National Forum urges CMS to pay attention to the potential unintended consequences affecting those at greatest risk, including rural America and other underserved communities. The ESRD PPS updates assume that medications inclusive to the bundle are appropriate for all patients. The ESRD PPS base rate operates as a flat increase regardless of severity of health status or whether the patient takes phosphate binders or not. This is not a patient-centered approach to evidence-based care. We recommend that CMS:

- Account for higher-severity or higher-need populations to avoid recreating financial incentives that restrict access.
- Proactively track phosphate control outcomes in the 12 months after the transition from TDAPA to the base rate. Accomplishing this ahead of the new ESRD QIP starting in PY 2029 provides up-to-date data rather than waiting for a retrospective review.

The National Forum understands that CMS has the unique challenge of balancing the cost to taxpayers while also providing access to evidence-based care for both patients and

providers. We urge CMS to follow the evidence and prioritize the best care for people living with CKD and ESRD.

Sincerely,

John M. Clymer
Executive Director
National Forum for Heart Disease & Stroke Prevention

References

1. Ahmad FB, Cisewski JA, Anderson RN. Mortality in the United States: Provisional data, 2025. Vital Statistics Rapid Release. 2025 Jul;(44):1–6. DOI:https://dx.doi.org/10.15620/cdc/252455.
2. Hou, W., Xie, P., Fu, Y., Wang, C., Wang, K., Sun, Y., Wei, W., Xu, L., & Su, C. (2026). Comparative Effectiveness and Safety of Phosphorus-Lowering Drugs for CKD 3-5 stages. Kidney Medicine, 8(5), 101331. https://doi.org/10.1016/j.xkme.2026.101331
3. Sampaio, M. S., Molnar, M. Z., Kovesdy, C. P., Mehrotra, R., Mucsi, I., Sim, J. J., Krishnan, M., Nissenson, A. R., & Kalantar-Zadeh, K. (2011). Association of Pretransplant Serum Phosphorus with Posttransplant Outcomes. Clinical Journal of the American Society of Nephrology, 6(11), 2712–2721. https://doi.org/10.2215/cjn.06190611
4. Medicare Payment Advisory Commission. (2024). OUTPATIENT DIALYSIS SERVICES PAYMENT SYSTEM. In Paymentbasics. https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_dialysis_FINAL_SEC.pdf
5. Karaboyas, A., Zhao, J., Ma, J., Moore, C., Saleem, N., Martin, K. J., Sprague, S. M., Smerdon, C., Pecoits-Filho, R., & Pisoni, R. L. (2024). Incorporation of Calcimimetics into End-Stage Kidney Disease Bundle. Clinical Journal of the American Society of Nephrology, 20(2), 218–228. https://doi.org/10.2215/cjn.0000000583
6. Fighting for Health: Mihi Wickamasinghe's Journey Managing Phosphorus on Dialysis – AAKP