

Submitted electronically to: www.regulations.gov

Aug. 26, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1830-P
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model [CMS-1830-P]

Administrator Oz,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its proposed rule *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model* ([ESRD Proposed Rule](#)).

NCPA represents America’s community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America’s most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

On November 14, 2024, CMS Transmittal 12962 implemented the 2-year TDAPA period specified in § 413.234(c)(1) for the following oral-only phosphate binders: sevelamer carbonate, sevelamer hydrochloride, sucroferric oxyhydroxide, lanthanum carbonate, ferric citrate, and calcium acetate. On December 12, 2024, that transmittal was rescinded and replaced by Transmittal 12999. The TDAPA payment period began on January 1, 2025, and will continue through December 31, 2026. TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer’s invoice.

In the CY 2025 ESRD PPS final rule (89 FR 89197), CMS estimated that total ESRD PPS spending for phosphate binders would be approximately \$870 million in CY 2025. CMS is revising this estimate for this CY 2026 ESRD PPS proposed rule based on analysis of the most current 72x claims data from January 2025, when utilization first appeared on the claims, through March 2025. In January, CMS observed that total spending was approximately \$14 million, whereas in February and March CMS observed that total spending was approximately \$30 million and \$34 million, respectively. Projecting forward using the level of utilization and pricing that CMS observed in March 2025, CMS estimates approximately \$380 million in spending for phosphate binders in CY 2025, of which 20 percent, or approximately \$80 million would be attributed to beneficiary coinsurance amounts.

Similarly, using the most current 72x claims data from March 2025 CMS have estimated CY 2026 spending using the level of utilization and pricing that CMS observed in March 2025. In applying that average to each month in 2026, CMS estimates approximately \$410 million in spending of which 20 percent, or approximately \$80 million, would be attributed to beneficiary coinsurance amounts.

CMS intends to further revise the estimates for DefenCath, Vafseo, and the phosphate binders for the CY 2026 ESRD PPS final rule based on updated utilization and price information. In the CY 2025 ESRD PPS final rule, effective Jan. 1, 2025, CMS incorporated oral-only phosphate binders into the End-Stage Renal Disease Prospective Payment System bundled payment, stating that these therapies are no longer separately billed under Medicare Part D. Patients' previous access to phosphate-lowering therapies (PLTs) through Medicare Part D was an essential lifeline for individuals managing kidney disease. NCPA continues to oppose the bundling of such services,¹ as it threatens to limit access to these therapies at community pharmacies, raise out-of-pocket costs, and undermine care quality for vulnerable patients.

PLTs are critical treatments for managing kidney disease, but recent studies² have shown past experience with bundled ESRD medications shows significant declines in the use of innovative and more effective therapies, especially for minoritized patients. Moving PLTs into the ESRD bundle would likely replicate this trend, restricting access to vital medications and jeopardizing patient outcomes.

Moreover, this change requires PLTs to be dispensed through dialysis centers instead of community pharmacies. Unlike pharmacies, dialysis centers are not best-equipped to manage the high volume of oral medications ESRD patients require—often 100-300 pills per month. Furthermore, pharmacists are highly trained healthcare professionals with in-depth knowledge of medications, their effects, interactions, and proper usage. Pharmacists are trained to catch potential errors in prescriptions, such as incorrect dosages, dangerous drug interactions, or conflicting treatments. This expertise significantly reduces the risk of harm to patients.

¹ See [NCPA letter to Congressional leadership](#), 26 Nov 2024.

² See Karaboyas et al, "[Incorporation of Calcimimetics into End-Stage Kidney Disease Bundle.](#)" *CJASN* Feb 2025.

Community pharmacists' personalized care is vital to ensuring patients receive appropriate medications tailored to their needs. Bundling these services would disproportionately harm underserved communities. Chronic kidney disease disproportionately affects Black, Hispanic, and Native American populations and those with limited healthcare access in rural communities. Community pharmacies, often the only accessible healthcare provider in both remote and urban areas, play a crucial role in addressing these disparities.

CMS currently holds LTC pharmacies to strict delivery timelines and compliance packaging requirements for medications under 42 CFR §423.154, yet contracted partners of dialysis providers serving the same patients, who reside in long-term care facilities, are not held to these same standards. This disparity allows dialysis centers to send ESRD medications to LTC pharmacies in improper packaging, creating workflow inefficiencies and safety challenges. These packaging issues also place additional burdens on nursing staff, who must spend extra time sorting, organizing, and preparing medications for administration, diverting attention away from direct patient care. **NCPA recommends CMS enforce the compliance packaging requirements to ensure dialysis providers meet the same standards as LTC pharmacies.**

Cost Estimations are Inaccurate Due to Failure of Pharmacist and Pharmacy Technician Inclusion. When CMS transitions the payment for PLT into the bundle payment, it failed to calculate the increased cost of pharmacists and pharmacy technicians associated with the appropriate and safe dispensing of these medications. Now that CMS has transitioned the payment, dialysis providers are required to have pharmacists and technicians and/or contract with pharmacies to provide the necessary dispensing services associated with PLTs.

At present, Table 2 of the crosswalk to Bureau of Labor Statistics (BLS) occupation classifications for ESRD facilities currently omits pharmacists and pharmacy technicians, despite their direct involvement in medication management following the inclusion of PLT into the bundle payment. Inclusion of pharmacists, technicians and their professional services in Table 2 is essential to accurately reflect the true cost to safely deliver medications to patients, regardless of their care setting.

Conclusion

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the ESRD proposed rule. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

A handwritten signature in black ink, appearing to read 'Steve Postal', with a long horizontal stroke extending to the right.

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association