



August 24, 2026
The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, D.C. 20001

RE: CMS-1846 Medicare Program; CY2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury Dialysis (AKI) Payment, and ESRD Quality Incentive Program

Dear Administrator Oz,

On behalf of the more than 37,000,000 Americans living with kidney diseases and the 22,000 nephrologists, scientists, and other kidney health care professionals who comprise the American Society of Nephrology (ASN), thank you for the opportunity to provide comments on the Calendar Year 2027 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 proposed rule.

Chronic kidney disease (CKD) is a progressive condition characterized by the gradual loss of kidney function. It affects approximately 37 million Americans, or about 1 in 7 adults, and its prevalence is projected to rise. CKD poses an increasing public health crisis, resulting in considerable morbidity and growing health care expenditures. The U.S. Medicare program spends more than \$150 billion each year managing kidney diseases, including \$50 billion for kidney failure patients alone. ASN believes it is essential for the nation to reduce the burden of kidney diseases on individuals, their families, and the health care system overall. This priority aligns with the Trump Administration's chronic disease prevention efforts to Make America Healthy Again (MAHA).

In this letter, ASN addresses CMS's proposed changes to the ESRD Prospective Payment System (ESRD PPS) and ESRD Quality Incentive Program (ESRD QIP). ASN has submitted a separate letter that addresses the Requests for Information (RFIs) present in the proposed rule.

PROSPECTIVE PAYMENT SYSTEM (PPS)

a. Incorporation of Phosphate Binders into the ESRD PPS Base Rate

ASN supports CMS's proposed methodology to include phosphate binders in the base rate by adding a per-treatment payment amount for these therapies, calculated in the manner proposed by CMS. ASN also supports CMS's proposal to incorporate the operational costs needed to supply phosphate binders into the base rate, accounting for storage, distribution, staffing, and administrative expenses unique to the high-volume, multi-product nature of phosphate binder therapy.

b. Updates to Post-TDAPA Add-On Payment Calculations and Conditional ASP Policy

ASN recognizes CMS's rationale for more frequent calculation of the post-TDAPA add-on payment adjustment to better align payment amounts with actual utilization of products. However, ASN does not support CMS's proposal to calculate the post-TDAPA add-on payment quarterly. Quarterly calculations could result in more rapid reductions in add-on payment rates, removing funds from the system more quickly while dialysis facilities continue to face challenges managing existing drug inventories and associated costs. More frequent adjustments could also introduce additional uncertainty and reduce transparency for dialysis facilities, exacerbating the very patient access concerns that the post-TDAPA add-on payment is intended to address.

ASN recommends that CMS instead calculate the post-TDAPA add-on payment adjustment every six months. A six-month calculation period would provide CMS with more robust and stable utilization data while allowing for more responsive updates to payment amounts than the current methodology. This approach would strike an appropriate balance between accurately reflecting utilization and maintaining greater predictability and payment stability for dialysis facilities.

ASN expresses deep concern over CMS's proposal to modify the conditional ASP policy such that the post-TDAPA add-on payment adjustment would stop in the next quarter after a non-submission of ASP data. The post-TDAPA add-on payment adjustment was established to support timely access to innovative treatments by providing dialysis facilities with additional payment stability as new therapies enter the ESRD PPS. Abruptly ending this payment adjustment due to a manufacturer's non-submission of ASP data, a scenario that is beyond the control of clinicians and providers, could create uncertainty around continued coverage and availability of these therapies, potentially limiting patients' ability to initiate or maintain access to clinically appropriate treatments.

ASN recommends that CMS consider safeguards to prevent interruptions in patient access to post-TDAPA therapies when ASP reporting requirements are not met. Any modifications to the conditional ASP policy should preserve continuity of care for patients currently receiving these therapies and avoid creating circumstances in which

patients lose access to clinically appropriate treatment due to administrative or reporting challenges.

c. Restructuring of the Low-Volume Payment Adjustment (LVPA) Methodology

ASN supports CMS's proposal to restructure the LVPA to establish six tiers and increase the treatment volume cap to 8,000 treatments annually. ASN believes that by establishing more gradual tiers, CMS can better align payments with the operational realities of low-volume facilities while reducing incentives that may limit patient access to dialysis services.

A more graduated LVPA structure recognizes that facilities serving smaller patient populations often face unique challenges, including lower economies of scale, fixed operational costs, and challenges maintaining access to care in rural and underserved communities. Expanding the tier structure would provide a more equitable approach that better accounts for differences in facility volume while supporting continued availability of dialysis services for patients who rely on these facilities.

ASN appreciates CMS's efforts to address the cliff effect and recommends finalizing a revised LVPA methodology that promotes stability for low-volume facilities without creating unintended barriers to facility growth or patient access.

d. Updates to the Home and Self-Dialysis Training Add-On Payment

ASN supports CMS's proposed increase to the home and self-dialysis training add-on payment to reflect current wage levels. However, ASN urges CMS to implement this update without a corresponding reduction to the ESRD PPS base rate. Because the training add-on payment adjustment factor has been increased, adjusting for inflation since the CY 2017 ESRD PPS final rule, applying a budget neutrality adjustment to offset the full impact of this update would disproportionately reduce the ESRD PPS base rate. ASN therefore recommends that CMS finalize the proposed update without applying a budget neutrality adjustment.

Going forward, ASN recommends that CMS update the home and self-dialysis training add-on payment on an annual basis using the most recent available Bureau of Labor Statistics (BLS) wage data. Regular updates would help ensure that the payment remains aligned with the costs of providing training and avoid large, infrequent adjustments that could result in disproportionate impacts to the ESRD PPS base rate.

e. Pediatric ESRD Payment Methodology Changes Following TPEAPA Expiration

ASN strongly opposes CMS's proposed changes to pediatric ESRD payment following the expiration of the Transitional Pediatric ESRD Add-On Payment (TPEAPA) on

December 31, 2026. Specifically, ASN objects to using facility volume as a basis for adjusting pediatric dialysis payment.

Using treatment volume as a proxy for the increased costs associated with pediatric dialysis fundamentally misunderstands pediatric dialysis care. Costs in pediatric dialysis care are driven by clinical complexity, specialized staffing needs, pediatric-specific equipment, and tailored supplies—not by high-volume operational efficiencies. In addition, CMS’s proposed methodology may unfairly penalize pediatric centers that are not low volume but still bear significantly increased fixed costs for the pediatric population without reflecting their actual expenditures.

Importantly, ASN also notes that the fact that pediatric dialysis care is more expensive does not mean that dialysis care for adults is less expensive. ASN urges that the needed increases in the reimbursement for the care of children requiring dialysis not be cost-neutral.

CMS has previously acknowledged that the standard pediatric case-mix adjustment fails to capture these costs, which is why the 30 percent TPEAPA add-on was established. Building on that recognition, ASN recommends the following path forward:

- Establish a Permanent Pediatric Adjustment: CMS should utilize the data gathered during the TPEAPA period to create a permanent, specialized pediatric payment adjustment rather than relying on volume-based penalties.
- Convene a Technical Expert Panel (TEP): If CMS determines additional data is required, the agency should convene a TEP to evaluate pediatric resource utilization and design a methodology grounded in actual clinical costs.
- Universal Application of LVPA: If CMS does not establish a permanent adjustment, the Low-Volume Payment Adjustment (LVPA) should be applied to all facilities providing pediatric dialysis, regardless of volume. This avoids penalizing high-volume specialized centers and ensures pediatric patients treated in predominantly adult facilities are not disadvantaged.

ASN urges CMS to prioritize simplicity and predictability in any update to pediatric payment methodology. Frequent changes to pediatric dialysis payment policy and the administrative requirements associated with the TPEAPA have created significant burdens for pediatric programs, particularly those embedded within predominantly adult facilities. A straightforward, predictable payment methodology would reduce administrative burden while ensuring that payment appropriately reflects the resources required to provide pediatric dialysis.

ESRD QUALITY INCENTIVE PROGRAM (QIP) CHANGES

a. Proposed Inclusion of the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients Clinical Measure

As previously expressed during Battelle's Partnership for Quality Measurement (PQM)'s Fall 2025 Endorsement and Maintenance (E&M) Measure Cycle and the 2025 Measures Under Consideration (MUC) Measure Cycleⁱ, ASN has significant concerns with the Percentage of Chronic Hyperphosphatemia in Dialysis Facilities measure.

While we recognize that including phosphate-lowering medications in the prospective payment system may justify a quality measure to guide appropriate use, we are concerned that the evidence supporting the proposed metric is derived solely from observational data rather than robust clinical trial-based evidence, and, therefore, there is considerable uncertainty as to whether the proposed metric will improve clinical outcomes. For example, no published clinical trials have established a serum phosphate range associated with improved outcomes, and neither the proposed threshold nor the hypoalbuminemia exception included in the measure is supported by high-quality data. In clinical practice, some patients have phosphate levels above 6.5 mg/dL for periods of time that reflect improvements in dietary intake, which should not be discouraged by this type of measure. Similarly, other people may experience nausea and other adverse symptoms with phosphate lowering medications.

ASN again highlights that the threshold in the proposed metric is currently being studied in a large, international, randomized clinical trial (details available at <https://clinicaltrials.gov/study/NCT03573089>), which is comparing intensive phosphate lowering to a liberal phosphate target of 6.2 to 7.8 mg/dL. Additionally, ASN notes that the day of the week that phosphate is assessed may influence the serum phosphate level in dialysis. Given the lack of high-quality supporting evidence for the proposed threshold and the reasonable possibility that the ongoing clinical trial testing this question will be negative, showing no benefit associated with a lower phosphate target, ASN encourages CMS to await the results from the ongoing clinical trial before implementing a metric that enforces this uncertain target.

b. Proposed Updates to the National Healthcare Safety Network Bloodstream Infection (NHSN BSI) Clinical Measure

ASN supports CMS's proposal to update the National Healthcare Safety Network Bloodstream Infection (NHSN BSI) clinical measure to use 2023 baseline data and additional facility-level characteristics. Updating the baseline period to 2023 provides a more accurate, contemporary benchmark for evaluating facility performance, reflecting post-pandemic clinical operations and patient care practices. Furthermore, refining the risk adjustment methodology to account for facility-level characteristics ensures that performance scoring more fairly evaluates dialysis facilities treating higher-risk, clinically complex patient populations. Appropriate risk adjustment is critical to preventing unintended penalties on facilities that care for complex patients, including those with higher proportions of catheter use or elevated social risk factors.

c. Proposed Removal of the Medication Reconciliation (MedRec) Reporting Measure

ASN strongly opposes CMS's proposal in the CY 2027 ESRD PPS proposed rule to remove the Medication Reconciliation (MedRec) reporting measure from the ESRD QIP beginning in PY 2029. Eliminating this measure would create a significant gap in patient safety oversight and undermine clinical quality across the outpatient dialysis setting.

CMS asserts that consistently high performance and reporting burden mean the costs of the measure outweigh its benefits. ASN strongly disagrees. High performance is not evidence that medication reconciliation is redundant or burdensome without value; rather, it demonstrates that QIP inclusion has helped establish this critical safety practice as an institutional standard of care.

Dialysis patients manage complex drug regimens, often taking an average of 10 to 12 daily medications prescribed by multiple clinicians. Given frequent hospitalizations and care transitions, this population is exceptionally vulnerable to adverse drug events, dosing errors, and dangerous drug interactions. Removing MedRec would eliminate a vital accountability structure and risk breakdowns in post-hospital care coordination. ASN urges CMS to retain the MedRec reporting measure in the ESRD QIP to protect patient health and prevent avoidable hospitalizations.

d. Concerns Regarding Mid-Year Specification Changes to the Kt/V Dialysis Adequacy Measure Outside Established Rulemaking

ASN is concerned that CMS' mid-year change to the Kt/V Dialysis Adequacy measure specifications, including the exclusion of patients receiving hemodiafiltration (HDF), was made outside of the established rulemaking process. This change substantively alters the measure denominator and may affect facility performance under the ESRD QIP.

ASN believes CMS should not make substantive changes to ESRD QIP measure specifications outside of the processes established for the program. Under 42 CFR § 413.178(c)(3), CMS is required to use formal notice-and-comment rulemaking to make substantive updates to ESRD QIP measure specifications. Bypassing standard rulemaking prevents the kidney care community, clinical experts, and participating facilities from evaluating the scientific justification, operational feasibility, and potential unintended consequences of technical metric changes.

Conclusion

ASN appreciates the opportunity to comment on the CY2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury Dialysis (AKI) Payment, and ESRD Quality Incentive Program proposed rule. To discuss this letter further, please contact Lauren Ahearn, ASN Senior Policy and Government Affairs Coordinator, at lahearn@asn-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Sam M. Parikh". The signature is fluid and cursive, with the first name "Sam" and last name "Parikh" clearly distinguishable.

Samir M. Parikh, MD, FASN
President

ⁱ https://www.asn-online.org/policy/webdocs/Measures_Under_Consideration_MUC_2025_Comment_Letter.pdf