August 24, 2026

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20001

Re: KCP Comments to CMS-1846-P: CY 2027 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Acute Kidney Injury Dialysis (AKI) Payment, and ESRD Quality Incentive Program ("CY 2027 ESRD PPS Proposed Rule")

Dear CMS,

Kidney Care Partners (KCP) appreciates the opportunity to submit comments to the CY 2027 ESRD PPS Proposed Rule.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, researchers, innovators, transplant coordinators, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD). Our policy priorities align with longstanding goals of CMS and this Administration to enhance disease awareness and education to inform patients' choice of treatment modality; to ensure that Medicare payments reflect and incentivize the provision of high-quality care; and to promote innovations that can make a real difference for Americans living with kidney disease.

Our organization and our members stand ready to partner with CMS and think critically about the future of kidney care, as Medicare redoubles efforts to reward outcomes improvement and enable innovation – rather than maintaining a challenging *status quo* for people with CKD. KCP appreciates and supports CMS' proposal to recognize phosphate binder therapy within the ESRD PPS base rate available for each patient. We are also pleased to provide feedback to CMS' requests for feedback on various aspects of current and future policy for Medicare's ESRD PPS, with initial responses to the Agency's Requests for Information (RFIs) enclosed in Appendix 1. Given the complexity of these RFIs and their volume, we ask that CMS continue to engage with stakeholders on these important topics following the comment period, through a reissuance of these RFIs and potentially through more rigorous and interactive mechanisms, such as a stakeholder town hall, kidney community workgroup, or technical expert panel (TEP).

KCP also remains concerned that Medicare's ESRD PPS is overly focused on cutting payments, at the expense of the patient-centered care model needed to improve health outcomes for Medicare beneficiaries with ESRD. While we agree that the topics addressed in the RFIs are important, we are concerned that efforts to implement these changes will be less effective if layered onto an ESRD PPS that has been weakened by inadequate annual updates, repeated budget-neutrality reductions to the base rate, and an add-on payment system that can limit (rather than facilitate) access to innovative therapies and technology. For example, although KCP appreciates CMS' continued focus on achieving payment adequacy for low-volume treatment facilities and providing sufficient support for home dialysis training and education, we strongly believe that efforts like these are undermined by the proposed application of a budget-neutral reduction to the base rate. In addition, KCP is disappointed that, despite many stakeholder comments over many years and consistent engagement with CMS, the Proposed Rule does not address the urgent reforms needed to ensure the "innovation" programs of the ESRD PPS (TDAPA, TPNIES, and the post-TDAPA period adjustment) actually encourage research, development, and access for groundbreaking treatments that can improve the health and lives of people with ESRD.

KCP and its members are deeply committed to caring for this particularly vulnerable beneficiary population. We support the Agency's goals to promote efficient resource use and deliver better value for individuals with ESRD and the Medicare Program. Unfortunately, policy decisions made over the past 15 years have eroded payment adequacy under the ESRD PPS and increasingly strained its ability to achieve those intended goals. We believe that addressing these challenges will require more comprehensive reform, and KCP looks forward to continuing to work with CMS on this fundamental issue.

In response to the specific policy proposals in the CY 2027 Proposed Rule, we offer the following comments.

1. **KCP supports CMS' proposal to incorporate payment for phosphate binders into the ESRD PPS base rate beginning in CY 2027 and offers two technical recommendations to improve implementation of this policy.**

KCP supports CMS' proposal to include phosphate binders in the ESRD base rate by adding a per-treatment payment amount for the cost of these therapies, along with the added operational costs incurred by dialysis facilities to administer and supply phosphate binders to beneficiaries. For a class of drugs that had already been marketed and used within the ESRD patient population for decades, we believe a two-year TDAPA period was sufficient to collect utilization and pricing data to inform the drugs' incorporation into the ESRD PPS base rate.

In addition, we agree with and support CMS' proposal to exclude Q1 2025 phosphate binder utilization data from the methodology to calculate the base rate adjustment for phosphate binders, for the reasons stated by CMS. Our dialysis organization members also observed that Q1 2025 utilization of phosphate binders was artificially low because many patients entered 2025 with existing supply from prior year Part D pharmacy dispensing. Accordingly, new phosphate binder dispensing under TDAPA was not immediately needed for certain patients in Q1 2025. This experience further supports CMS' determination to exclude Q1 2025 data.

In connection with CMS' proposal, KCP offers two recommendations. First, CMS proposes to update its calculation of the ESRD PPS base rate addition for phosphate binders in the final rule with the most recent available claims data, which CMS anticipates will include dates of service from April 1, 2025, ***through July 31, 2026***. KCP requests that in the final rule, CMS utilize claims with dates of service reflecting the 12-month period from April 1, 2025, ***through March 31, 2026***. The data for this 12-month period are available for public review and comment during the notice-and-comment period, providing an adequate opportunity for evaluation and commenter input. We believe this period reflects the most recent available data to support a final rule update fully available for public comment, which would not occur if CMS used claims data after Q1 2026.

Second, KCP supports CMS' proposal to incorporate the additional operational costs needed to supply phosphate binders into the base rate, to account for dialysis organizations' new costs associated with storage, distribution, staffing, and administrative expenses for the high-volume, multi-product nature of phosphate binder therapy. To account for these operational costs throughout the two-year TDAPA period for phosphate binders, CMS was correct to maintain a consistent monthly payment of $36.41. Those operational costs have remained the same moving into 2027, if not increased. As CMS has recognized, phosphate binder therapy represents a uniquely complex and resource-intensive component of dialysis care, which extends well beyond medication dispensing. Phosphate binders require continuous clinical management driven by individualized dosing, multiple therapeutic options, patient-specific tolerability considerations, formulary requirements, and ongoing adherence challenges. Treatment requirements often change over time in response to fluctuations in phosphorus control, nutritional status, dietary intake, gastrointestinal tolerance, and overall clinical condition, making phosphate binder management an ongoing care process rather than a one-time prescribing event.

While a minor portion of these costs scale with utilization of these therapies, most of the operational requirements are both necessary and relatively consistent to offer any level of facility-led phosphate binder supply to patients, regardless of volume (e.g., new areas for storage, new pathways for distribution, and new staff time devoted to management). Successful phosphate binder management requires substantial infrastructure to support clinical assessment, laboratory monitoring, therapy optimization, adherence interventions, safety oversight, and ongoing care coordination. For these reasons, to calculate the amount for the operational costs to include in the base rate, KCP strongly encourages CMS to add an amount that corresponds to the ***current*** add-on payment amount for operational costs for phosphate binder supply.

2. KCP requests that CMS <u>not finalize</u> its proposal to update post-TDAPA add-on payment adjustment amounts on a quarterly basis.

KCP strongly opposes CMS' proposal to update the post-TDAPA add-on payment adjustment on a quarterly basis, which would reverse current CMS policy to update this adjustment on an annual basis. We believe that CMS was correct in adopting its policy to set the post-TDAPA add-on payment adjustment on an annual basis, using the latest data available as of publication of the ESRD PPS final rule. CMS rightfully acknowledged just three years ago that routinely updating the post-TDAPA add-on payment adjustment quarterly will make it more

difficult for ESRD facilities to estimate payments and budget for the provision of patient care. That important consideration has not changed.

KCP is concerned that the proposed quarterly ASP updates for the post-TDAPA add-on payment adjustment will reduce incentives for innovation, harm patient access to innovative therapies, and complicate operational feasibility.

The post-TDAPA add-on payment is intended to provide an adjustment to the ESRD PPS to account for a new drug. By creating a 3-year post-TDAPA transition period, we understand CMS sought to further incentivize innovators and dialysis organizations to provide patients access to new drugs and biological products, as an access "bridge" between TDAPA and inclusion of the treatment in the base rate—not to track utilization and ASP changes for rate-setting purposes. We fear that quarterly adjustments to these payment rates would exacerbate the very patient access issue the post-TDAPA add-on payment is intending to address, by introducing less transparency and more uncertainty.

Dialysis organizations would not only face greater uncertainty, but they would be responsible for significant administrative burdens to make quarterly system updates for changing quarterly payment rates for all dialysis treatments across all facilities. This change would meaningfully differ from the quarterly updates that occur during the TDAPA period, when facilities understand that changing payment rates will only apply to the drugs and biologicals that they purchase and supply to specific patients. Facilities would not have the ability to anticipate and plan for quarterly payment adjustments because post-TDAPA add-on payment adjustments apply to all patients, regardless of whether a facility purchases the therapy or supplies it to an individual patient. The complexity of ASP calculations, data lag, and volatility will introduce significant instability into these processes. Unpredictable contracting disrupts formularies and threatens continuity of care. The post-TDAPA policy must remain stable to prevent volatile payment swings.

CMS frequently reminds stakeholders that the ESRD PPS is prospective in nature, with rates set on the best information available at the time of rulemaking. As CMS has considered but rejected similar mid-year changes to payment amounts in other prospective payment systems, CMS has explained that maintaining payment amounts throughout the year, with changes only considered in future rulemaking rather than in mid-year updates, is consistent with the prospective nature of Medicare's payment systems.[1] The same consideration applies here.

For these reasons, we urge CMS to preserve its original policy and withdraw the proposed change to update the post-TDAPA add-on payment adjustment on a quarterly basis. If the Agency were to consider finalizing this policy, at minimum, CMS should maintain its existing payment policy for therapies currently in the TDAPA or post-TDAPA periods. Stakeholders have relied on CMS' established policies for this period when establishing volume

[1] CMS, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Final Rule, 91 Fed. Reg. 49570, 49787 ("Consistent with the prospective nature of the IPPS and OPPS, we do not make mid-year changes to payment amounts, and any changes to payment amounts are considered in future rulemaking.") (Aug. 4, 2026).

forecasts, manufacturing capacity, purchasing plans, pricing policies, and clinical programs. The Agency recognized these reliance interests in the recent FY 2027 IPPS rule, when it significantly modified NTAP and transitional pass-through eligibility policies for breakthrough medical devices, but adopted a policy to "grandfather" devices that already achieved breakthrough designation. CMS concluded that maintaining current policies would be appropriate for those technologies that were approaching commercialization or already commercially available.[2] Those same considerations would apply to any change to the post-TDAPA period rules. Accordingly, while KCP urges CMS to not finalize its proposal, CMS should apply the same consideration and "grandfather" any currently available TDAPA or post-TDAPA treatments under the current annual payment adjustment authority.

3. KCP continues to urge that CMS use its regulatory authority to adopt policy changes that will facilitate patient access to real innovation in kidney disease care.

In the CY 2026 ESRD PPS Proposed Rule, CMS invited stakeholders to submit comments on how CMS' TDAPA policies could be improved in future rulemaking. Despite significant stakeholder engagement on that request, including a range of clear recommendations from KCP and our members, we were disappointed to see that CMS did not propose a single policy for CY 2027 that would meaningfully improve TDAPA, TPNIES, post-TDAPA, or other innovation-related payment policies. On the contrary, as noted above, KCP has serious concerns that the most significant proposal for the post-TDAPA add-on payment adjustment would *exacerbate* longstanding concerns and further undermine patient access to innovative therapies.

At this point, the evidence is overwhelming: Innovation funding for CKD-related conditions is uniquely broken, restricting investment and development of new treatments, and failing to provide long-term access for new therapies and technology that materially improve the health and lives of individuals with CKD. Kidney drug development has historically lagged behind other major chronic diseases. Research has shown that the number of randomized drug trials for ESKD lags far behind other therapeutic areas, like cancer and heart disease.[3,4] These therapeutic areas have more favorable and sustained reimbursement mechanisms than a two-year TDAPA period, coupled with a policy that provides for a permanent base rate adjustment only for new drugs not in an existing functional category.

For comparison, Medicare's payment systems for the hospital outpatient and hospital inpatient settings involve similar payment bundling policies as the ESRD PPS, and the innovation funding mechanisms in those payment systems apply rigorous eligibility criteria, similar to TDAPA and TPNIES. CMS confirms in the Proposed Rule that, as of today, there are **zero** drugs and biologicals continuing TDAPA payment status in CY 2027, and **zero** new or continuing TPNIES payments in CY 2027. In these other Medicare payment systems, we see:

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[2] *Id.* at 49787 ("We also agree that it would be appropriate to adopt a transitional approach to support the technologies already in advanced stages of commercial development or that may already be commercially available.").

[3] Heerspink HJL, List J, Perkovic V. New clinical trial designs for establishing drug efficacy and safety in a precision medicine era. Diabetes Obes Metab. 2018; 20(Suppl. 3): 14–18.

[4] Breyer MD, Susztak K. Developing Treatments for Chronic Kidney Disease in the 21st Century. Semin Nephrol. 2016 Nov;36(6):436-447. doi: 10.1016/j.semnephrol.2016.08.001. PMID: 27987541; PMCID: PMC5423404.

- **16** different device categories with transitional pass-through device status in CY 2027 (even before finalization of new devices discussed in the proposed CY 2027 OPPS rule);
- **73** different drugs and biologicals with transitional pass-through drug status for some portion of CY 2027; and
- **60** different drugs, biologicals, and devices with New Technology Add-on Payment (NTAP) status continuing into FY 2027 in the hospital inpatient setting.

These stark differences in the volume of new and effective treatments being offered in other settings of care governed by Medicare prospective payment systems are not simply due to the range of different conditions treated in the hospital, as compared to the dialysis center. TDAPA and TPNIES can and do extend to drugs, biologicals, and technologies with indications as varied as moderate and severe pruritus and the reduction of catheter-related bloodstream infections. The primary rate-limiting factors for kidney care innovation are the design elements of the innovation funding systems available within the ESRD PPS.

The problems that plague the ESRD innovation funding mechanisms are numerous, but they are ultimately fixable. CMS can begin by adopting the same types of policies that were proven to facilitate participation in hospital-based innovation funding mechanisms, including:

- Extending the TDAPA and TPNIES periods to a consistent three years for new drugs, biologicals, and technology (excluding currently available phosphate binders, which were already used consistently among ESRD patients and had established clinical practices, training, and utilization data in place)[5];
- Creating an alternative pathway to automatic TPNIES eligibility for breakthrough-designated medical devices; and
- Removing the artificial barrier between home-based and in-center capital equipment for TPNIES eligibility, allowing in-center capital equipment to qualify for TPNIES if it meets criteria.

KCP recognizes that CMS removed the alternative pathway for breakthrough-designated devices under Medicare's hospital inpatient and outpatient pathway systems, given questions about the benefits to the Medicare population of breakthrough-designated products used in the hospital setting. Unlike the hospital setting, breakthrough-designated devices that are approved or cleared for ESRD-related indications for use are undeniably new and relevant for the patients treated under the ESRD PPS. Because the ESRD PPS payment system is narrowly focused on people with ESRD – all of whom are potentially eligible for Medicare regardless of age – KCP does not believe the same questions and concerns would apply to an alternative pathway for TPNIES eligibility for breakthrough-designated devices that are approved or cleared for use in patients with ESRD.

[5] As noted above, KCP supports the two-year TDAPA period adopted by CMS for currently available phosphate binders, as well as CMS' proposal to add these drugs to the base rate as of January 1, 2027.

In addition to these changes, given the unique Medicare eligibility afforded to individuals with ESRD, and the high proportion of patients enrolled in Medicare Advantage (MA) plans, CMS should require MA plans to apply the same add-on payment policies as Medicare Part B.

We encourage CMS to work towards implementation of these necessary changes to ESRD PPS policy. While Congress has encouraged CMS to act on this request by putting forward key innovation-focused updates in the Kidney Care Access Protection Act (S.2730), we strongly believe CMS has the authority to adopt these provisions.

4. **KCP appreciates the routine rebasing and revision of the ESRD PPS market basket to reflect more recent costs and expenditures.**

KCP appreciates the need for regular rebasing and revision of the ESRD PPS market basket. As significant modifications to the market basket, labor-related share, and the wage index methodology result in significant facility-based payment adjustments, KCP would encourage CMS to continue to evaluate the overlapping effects of these policy updates on facilities' payment rates. Further transparency into the impacts of these changes, and how they interact with each other, would help stakeholders better understand how they may impact access to care.

5. **KCP continues to urge CMS to update the ESRD PPS market basket increase to account for years of insufficient payments due to recurring forecast errors.**

KCP continues to urge CMS to recognize and address the longstanding funding shortfall in the ESRD PPS caused by years of woefully inadequate market basket updates. KCP provided detailed feedback in last year's rulemaking cycle, which identified the cumulative market basket update underpayment for the ESRD PPS compared to other Medicare payment systems in the last 10 years. An update that better reflects the actual labor-related share for ESRD facilities may help on a forward-looking basis, but it will not make up for years of insufficient payment updates.

As KCP has noted in prior comments, a short-term fix would be to adopt the same forecast error adjustment policy that applies to skilled nursing facilities. While more work would be needed for a sustainable solution, this step would ensure that an inaccurate inflation forecast does not result in the permanent loss of funding that is supposed to be directed at patient care. Table 1 shows the cumulative impact of the missed forecasts by CMS' contractor on the ESRD PPS market basket update factor:

Table 1. ESRD PPS Market Basket Forecast Error Over Time

Forecast Error over Time

Source: ESRD Final Rules 2019-2026, CMS Market Basket Summary Data Q12026 release

Market Basket Base Year	2016				2020			
ESRD PPS Final Rule	2019	2020	2021	2022	2023	2024	2025	2026*
Unadjusted Final MB Update	2.1	2	1.9	2.4	3.1	2.4	2.7	2.9
Actual MB Inflation (Q4 market basket increase in each year Per IGI Global Methodology)	2.2	1.9	2.9	5.1	4.1	3.3	2.9	3.2
Final MB Update Compared to Actual (forecast miss)	-0.1%	0.1%	-1.0%	-2.7%	-1.0%	-0.9%	-0.2%	-0.3%

*CMS data; 2019-2025 actuals are historic data, 2026 "actual" is the contractor's updated forecast amount

The cumulative difference between the forecast and actual increases in costs is more than seven percent (7%) since 2019. Without adequate funding, providers cannot provide the services that patients require. To stop this continual loss of dollars from the ESRD PPS, KCP urges CMS to adopt the forecast error adjustment for CY 2027 that has been discussed during multiple rulemaking cycles. Specifically, we request that CMS adopt an increase to the base rate that accounts for the forecast error going back to 2019. Any further delays will continue to have a negative impact on patient access to high-quality renal dialysis services.

In addition, on a go-forward basis, KCP urges CMS to provide additional transparency into the forecasting data, methodology, and assumptions made by IHS Global Inc. (IGI) as it relates to the annual forecast for the ESRD market basket update. While CMS has previously described these models as "proprietary in nature," the continued use of IGI calculations to determine Medicare payment policy necessitates greater transparency and public stakeholder scrutiny, especially when those forecasts have fallen short so frequently over time. To adhere to the HHS and OMB Information Quality Guidelines requiring that "influential" financial and statistical information be based on data and studies that can be substantially reproduced – and that is otherwise subject to "a high degree of transparency about data and methods to facilitate its reproducibility by qualified third parties"[6] – we ask that CMS provide transparency and access to IGI data and methods, including through a limited distribution (e.g., a data use agreement or technical expert panel) if wide dissemination is not available.

6. KCP is highly concerned with proposed increases to the fixed-dollar loss (FDL) for outlier payment eligibility for adult and pediatric patients.

CMS proposes to increase the FDL amounts for adults by $100 and for pediatric patients by over $40, which would significantly narrow outlier payment eligibility as compared to 2026. While KCP recognizes that CMS must set annual thresholds with the intent of reaching the annual target of 1% of spending on outlier payments, we fear that unreliable data is being used to

[6] HHS Office of the Assistant Secretary for Planning and Evaluation, *HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public*, HHS Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated to the Public | ASPE (accessed Aug. 19, 2026).

support this increase, which will reduce outlier eligibility to fewer than half of the patient-months that qualified for outlier payments in 2026.

Specifically, CMS notes that the proposed increases to FDL and MAP for 2027 are primarily attributable to the projected utilization of drugs currently reimbursed through TDAPA, based on 2025 utilization and cost data, which may not accurately predict 2026 and 2027 outlier performance. This continued volatility in outlier thresholds highlights the insufficiency of the outlier policy to attempt to offset per-patient costs for new drugs and biological products recognized as renal dialysis services. KCP strongly recommends continued exploration by CMS and stakeholder engagement to develop a more reliable and consistent policy to reimburse providers for these costs.

Recent history shows CMS has repeatedly underpaid outlier payments at an amount below the 1% annual spending target, and we believe the proposed significant increases in MAP and FDL amounts will have the same result. KCP urges CMS not to overestimate the costs for these treatments and their effect on the outlier thresholds.

7. **KCP appreciates CMS' recognition that current ESRD PPS payments do not achieve payment adequacy for most dialysis facilities, including those that provide more than 4,000 annual treatments. We urge CMS not to apply a budget-neutral reduction to the base rate to account for any update to the LVPA.**

KCP appreciates CMS' recognition that many facilities – not only those that offer fewer than 4,000 treatments per year – incur per-patient costs in excess of the base rate payments they receive. As CMS continues to evaluate potential adjustments to the LVPA policy and other payment policies, it is important to recognize that CMS' own analysis clearly demonstrates that from 2022 to 2024, most Medicare facilities experienced per-patient costs that exceeded Medicare payments for patient care. This observation is important not only to LVPA policy, but the larger concerns expressed with the ESRD PPS payment system.

Most relevant to this policy, the recognized insufficiency of base rate payments is only worsened when CMS proposes to apply a budget-neutral reduction to the base rate as an offset for any potential expansion of the LVPA. Increasing payment for some locations, while decreasing base rate payments for all others, creates a self-reinforcing cycle of payment erosion that further destabilizes the payment system. For instance, CMS proposes to cut off eligibility for an expanded LVPA policy at 8,000 annual treatments, based primarily on the estimate that at this volume and greater, Medicare payments account for 99% of facilities' anticipated costs. If the only way to increase payment for facilities under 8,000 treatments is to take that money from facilities delivering 8,000 or more treatments, the facilities on the lower end of the 8,000 to 9,999 treatment band will face further underfunding – lowering payment adequacy below the 99% threshold.

For this reason, KCP urges CMS not to apply a budget-neutral reduction to offset any anticipated payment increase from an expanded LVPA. Where the intent of the LVPA policy is to ensure facilities can deliver patient services regardless of facility size and per-patient cost expectations, CMS should exempt any LVPA program change from a budget-neutral offset.

8. **KCP supports the proposed update to the home and self-dialysis training add-on payment, but we urge CMS to implement this change without a corresponding reduction to the ESRD PPS base rate.**

KCP appreciates the recognition by CMS that the home and self-dialysis training add-on payment has not been updated in 10 years to reflect the rising costs of providing this service to patients. While KCP supports CMS' proposal to update the payment rate to reflect current wages, we are again concerned that CMS proposes to impose a reduction to the ESRD PPS base rate to account for this overdue true-up on rates in a "budget-neutral" manner.

This adjustment to the payment rate is not caused by any change in methodology or adjustment to the scope of the add-on payment, but rather reflects more than 10 years of annual wage increases that have not been applied to the nursing time required for the home and self-dialysis training add-on. While the training portion included in the ESRD PPS base rate in 2011 has been increased by annual market basket increases, the add-on payment has been fixed in amount since 2014. In fact, KCP has not identified a clear statutory or regulatory basis for CMS to apply a budget-neutral reduction in CY 2027 based on this routine update to the home and self-dialysis training add-on payment.

Consistent with routine base rate increases over time, we urge that this routine cost update to the add-on payment, using 2023 wage data, be made without a corresponding budget-neutral adjustment to the base rate.

9. **KCP urges CMS to extend the transitional pediatric ESRD add-on payment adjustment (TPEAPA) while the Agency continues to develop more reliable data on pediatric dialysis costs.**

KCP has appreciated CMS' recognition over the last few years, as well as in the Proposed Rule, that pediatric dialysis services are substantially more resource-intensive than adult dialysis services. We believe that implementation of the TPEAPA was an important and necessary step to recognize those costs, while collecting more targeted pediatric data. Unfortunately, as CMS recognized in the Proposed Rule, there continue to be significant limitations in pediatric-specific ESRD cost reporting, particularly for hospital-based facilities. These limitations were highly prevalent in the years CMS used to evaluate pediatric dialysis costs (2022 and 2023), before new guidance and changes were issued in 2024 for hospital-based facilities. Even after that new guidance, stakeholders have reported continuing challenges for hospital-based pediatric facilities to report ESRD-related costs. KCP urges CMS to continue TPEAPA and continue to collect cost data to inform any permanent update to the case-mix adjusters for pediatric dialysis patients.

To ensure that CMS sets a final add-on payment rate that adequately reflects the cost of pediatric ESRD care, we urge the Agency to consider extending the temporary TPEAPA until it has the data needed to set a sustainable final add-on payment amount. We understand that CMS has not yet updated the hospital cost report form, which hospitals use to report data on staffing and supply costs, to include data on pediatric-specific staff and supplies used for dialysis. Children's hospitals have limited experience with Medicare cost-reporting, since children with ESRD are typically the only Medicare beneficiaries treated in children's hospitals, so there remains a disconnect between the data requested by CMS and how it is tracked by children's

hospitals. For example, specially trained staff, including child life specialists, dietitians, and social workers, are also providing non-dialysis patient care in the children's hospital, which can make it a challenge to appropriately allocate and report staff time. To collect the necessary data, we recommend that CMS update the hospital cost report form to include pediatric-specific staffing and supplies so that this data can easily be captured.

Using inadequate data to determine a permanent pediatric adjustment will have real consequences for the hospitals and providers who treat children with kidney disease, particularly given the ongoing pediatric nephrology workforce shortage. Without sustainable reimbursement to pediatric dialysis facilities, it becomes difficult to retain the specially trained staff who deliver quality care to this vulnerable population, potentially limiting access and resulting in worse health outcomes.

Rather than replacing the current pediatric payment adjustment with revised pediatric modifiers and adjustments to LVPA policy for pediatric dialysis centers, KCP requests that CMS continue the current TPEAPA for CY 2027 and then convene a TEP charged with: (i) identifying the remaining gaps in pediatric ESKD cost and utilization data, (ii) recommending an appropriate data collection strategy, (iii) evaluating appropriate methodologies for future multiplier adjustments, and (iv) ensuring that Medicare payment policy reflects the clinical and operational realities of pediatric dialysis care.

10. KCP appreciates and supports CMS efforts to update the ESRD Quality Incentive Program (QIP) for PY 2029.

KCP appreciates CMS' continued focus on modernizing the ESRD QIP. We are pleased to see the Proposed Rule align with KCP's comments in prior years, including our recommendation to remove the hypercalcemia measure; to retire a similar number of measures if the Agency proposes to add new measures; and to focus QIP measures on the original Congressional goals of improving patient outcomes, creating greater transparency, and incentivizing providers to deliver quality care. Based on these standards and consistent with the Agency's discussion in the Proposed Rule, KCP supports the removal of two reporting measures, the Medication Reconciliation (MedRec), and the COVID-19 Vaccination Coverage among HCPs. The MedRec measure evaluates an important aspect of patient care, but as the developer and owner of the MedRec measure, KCP recognizes the fact that compliance with this measure is "topped out" under the ESRD QIP. We would encourage CMS to continue to work with stakeholders to evaluate ways to account for proper medication reconciliation for patients with ESRD.

KCP also supports CMS in its proposal to replace the hypercalcemia reporting measure with the Facility-Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients (Hyperphosphatemia) measure. Considering the statutory requirement that the QIP include a measure related to bone and mineral metabolism, the long-standing performance on the hypercalcemia measure, and forthcoming bundling of phosphate binders in CY 2027, we believe the Hyperphosphatemia measure is appropriate for inclusion in the QIP. KCP understands, however, that the implementation schedule to add this measure to the QIP would rely on partial-year 2026 data, during a period when phosphate binders have not yet been incorporated into the

base rate. To appropriately set data and quality benchmarks, we recommend that CMS incorporate this measure as a Reporting Measure for the first year.

Lastly, KCP also supports CMS' 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 data to 2023 and revising the risk adjustment model to incorporate additional facility-level characteristics can help provide a more precise measure of patient outcomes in this important area. In prior comments, we have expressed concerns about significant under-reporting of dialysis-related events with the NHSN BSI measure, and we believe questions as to validity and reliability of the data remain. Beyond updating for more recent data, we would encourage CMS to continue to evaluate the measure for validity. We hope, however, that this measure will provide meaningful data in the coming years, as recent innovations aimed at reducing the incidence of bloodstream infections – such as DefenCath – transition through TDAPA and to the post-TDAPA payment periods, and as other technology and provider initiatives to address bloodstream infections are deployed.

11. KCP members have concerns with the potential inclusion of the Dialysis Facility Discussion of Patient Life Goals (D-PaLS) Patient-Reported Outcome Performance Measure (PRO-PM) in the ESRD QIP.

KCP agrees that well-being and achievement of life goals are important for all Americans, including individuals living with kidney failure. We believe, however, that the measures in the ESRD QIP should focus on those services that dialysis facilities provide so that they accurately reflect facility performance and support accountability for outcomes that can be directly impacted. Patients and patient advocates who work with KCP have repeatedly urged CMS not to adopt measures that are outside of this scope, or that are aspirational in nature rather than based in evidence. KCP maintains the position that the QIP should be focused on whether or not dialysis facilities are providing the renal dialysis services necessary to maintain the health of people living with ESRD.

As CMS requests feedback on the potential inclusion of the D-PaLS in the ESRD QIP, our members are concerned that dialysis facilities are not positioned to assist patients in incorporating all of the "patient life goals" the patients may desire into dialysis treatment planning, especially given the well-established clinical, financial, and social challenges of many patients receiving dialysis treatments. We are also not aware of clinical evidence supporting the ability of dialysis facilities to achieve improvement on this measure, or that would support further development of this performance measure for inclusion in the QIP. We urge CMS not to pursue adding the D-PaLS in the ESRD QIP, but instead to continue to engage with stakeholders on a more appropriate mechanism to address a patient life goals assessment.

* * *

Thank you again for providing KCP with the opportunity to provide comments on the Proposed Rule. Please do not hesitate to reach out to us if you have any questions. We appreciate

the opportunity to continue to work with you on making the Medicare ESRD benefit more patient-centric.

Sincerely,

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CSL Vifor
DaVita, Inc.
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Novartis
Nephrology Nursing Certification Commission
Pathalys Pharma, Inc.
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
The Rogosin Institute
U.S. Renal Care, Inc.
Unicycive Therapeutics, Inc.

APPENDIX 1

Initial Responses to RFIs

KCP and our members thank CMS for the opportunity to provide feedback on important issues related to the Agency's goal of advancing policies that increase patient choice through affordable alternative treatments for ESRD. We believe that receiving stakeholder feedback on complex and important policy questions is a necessary step in developing appropriate and well-informed public health policy, and we commend the Agency for initiating this process.

That said, the volume of RFIs and complexity presented by these issues requires much further analysis, engagement, and discussion than accommodated in a 60-day comment period, at the same time that stakeholders are developing responses to CMS' policy proposals for CY 2027. As CMS considers responses provided during this initial period, we ask that CMS re-issue these RFIs through a standalone comment process or with the CY 2027 final rule (i.e., as a final rule with comment) to facilitate additional engagement on these topics.

We look forward to continuing to collaborate with CMS, our member organizations, and other kidney care stakeholders to advance patient choice and improve kidney care delivery.

a. RFIs on Increasing Home Dialysis Uptake

KCP understands CMS' emphasis on measuring home dialysis uptake and continuation among Medicare FFS ESRD beneficiaries, as well as the recognition that increasing overall home dialysis depends partly on providing modality options and education at initiation of dialysis. We support efforts to examine the feasibility of achieving a more significant increase in utilization of home dialysis and to identify specific barriers to achieving that increase. We offer the following feedback to these RFIs:

i. Kidney disease education (KDE) and upstream modality preparation

We believe that education must be an ongoing part of the patient's journey, starting upstream at early CKD and continuing well past dialysis initiation. Specifically, we recommend including CKD stages 3b and 5, alongside stage 4, in KDE. Expanding access to stage 3b and 5 provides a continuous, comprehensive educational pathway that can significantly improve outcomes, slows disease progression, and controls costs. Stage 3b represents a "tipping point" in renal decline. Introduction of formal education at this point acts as a preventive security system against advancing further decline. Crucial dietary and lifestyle changes, prevention of cardio-vascular complications, and medication management are key to preventing progression beyond stage 3b. Including stage 5 patients in KDE would help to ensure a safe, planned transition, rather than a medical crisis. KDE education at this stage facilitates "optimal" and planned dialysis starts and could promote home dialysis selection and advanced care planning.

To facilitate home dialysis, CMS should allow primary care physicians and dialysis facilities to furnish and receive reimbursement for kidney disease education (KDE), support non-physician educators, and allow flexible delivery formats such as virtual and group sessions to

allow patients to continue education and revisit decisions as their condition and needs change. Patients who start dialysis emergently should still receive timely education through structured transitional programs.

KCP also encourages CMS to evaluate opportunities to reduce or eliminate beneficiary cost-sharing for KDE sessions. Beneficiaries are responsible for a standard 20% Part B coinsurance per session, after meeting their deductible. We believe there are opportunities to remove this amount, such as by recognizing KDE as an approved preventive service (under the National Coverage Determination (NCD) process). A 20% copay creates an unnecessary financial barrier for patients, many of whom are low-income. Because education delays the progression toward costly dialysis, we believe eliminating the Part B copay amount will ultimately lower long-term Medicare expenditures and improve patient health.

ii. Home dialysis training and workforce capacity

We encourage CMS to make training available to patients at any time during the course of dialysis treatment. CMS should support flexible strategies that help patients succeed during training, such as the availability of group training and off-hours sessions, along with the availability of home dialysis training centers of excellence to support rural patients. To support continuation of home dialysis, CMS should fund opportunities for retraining after the initial training period so that patients can stay confident and successful on home therapy over time and manage challenges as they arise. It would be important, however, for any such funding changes to reflect additional funding, rather than being implemented in a budget-neutral manner relative to the ESRD PPS.

With respect to workforce capacity, we appreciate the Agency's interest in addressing workforce barriers that may limit home dialysis uptake. KCP continues to support the ESRD Conditions for Coverage requirements that ensure qualified nephrology registered nurse (RN) involvement in home dialysis training and oversight. Home dialysis training extends well beyond teaching patients the technical steps necessary to perform a treatment. It requires individualized clinical assessment, patient and caregiver education, evaluation of competency and readiness for independent treatment, recognition and management of complications, and ongoing coordination of the patient's care. We recognize and value that these responsibilities require clinical judgment and expertise, and we continue to support the current requirement that qualified nephrology RNs oversee home dialysis training.

KCP also supports including other appropriately trained members of the interdisciplinary team, who can and should contribute to home dialysis education, training, and patient support, consistent with their qualifications and scope of practice. These professionals should complement the role of qualified nephrology RNs. As CMS knows, workforce shortages can present significant barriers to expanding home dialysis.

We encourage CMS to support policies that help strengthen the recruitment, training, and retention of qualified home dialysis RNs.

iii. Temporary and staff-assisted home dialysis

KCP is supportive of patients having access to temporary staff-assisted home dialysis during sensitive transition periods, such as following inpatient admission, outpatient surgery, or serious injury, to prevent modality failure. Whether this proposal is considered through regulatory or legislative means, however, it is essential that such benefits are not applied to the ESRD PPS in a budget-neutral manner.

KCP also encourages CMS to explore mechanisms to recognize respite care as a standard aspect of home programs to mitigate caregiver burnout. For example, CMS could support initiation and retention of home dialysis by offering "startup" payments for in-center self-dialysis training. CMS may also consider support for alternative care settings employed successfully in other countries, such as community dialysis houses, for home patients who may prefer to dialyze outside of the home. It is critically important, however, that these policies are not applied to the ESRD PPS in a budget-neutral manner.

iv. Payment alignment, incentives within the ESRD PPS and ESRD PPS cost report

As CMS considers payment alignment and incentives within the ESRD PPS to support home dialysis adoption, KCP would emphasize that innovation funding across the ESRD PPS, including for home dialysis, must be designed to achieve the goal of providing predictable financial support over a sufficient period of time to incentivize systems development and durable change.

The current scheme of innovation funding in the ESRD PPS is not designed to achieve that goal for in-center dialysis, unfortunately, but could be improved in the context of home dialysis. Potential payment incentives to support home dialysis adoption must be designed to support innovation, including add-on payment availability for innovative home dialysis drugs and biologicals. In addition, updated substantial clinical improvement criteria that focus on improving ease of use, reliability, and safety of home dialysis equipment and devices could facilitate better TPNIES recognition for new technology for home dialysis.

v. Access placement, referral and physician participation in home dialysis training

To better incentivize peritoneal dialysis (PD), the physician payment rate for PD catheter placement should be equalized with the rates for vascular access. CMS should also close the payment gap between home and in-center care, without diminishing reimbursement for providers relative to current payment rates.

Physician payment should account for time spent coordinating home training and care planning, with flexibility to use telehealth in the first 90 days.

vi. Skilled nursing facilities and transitional settings

CMS should remove barriers to home dialysis in skilled nursing facilities (SNFs) by modifying the payment structure to enable direct payment to dialysis providers, covering staff-assisted home dialysis, and supporting investments in technology that help SNFs avoid costly room buildouts and allow for better data-sharing across varied electronic health record (EHR) systems.

b. RFI to Advance Palliative Care for Dialysis Patients

KCP encourages CMS to adopt policies that support comfort, symptom management, quality of life, and achieving patients' end-of-life goals – rather than creating barriers to care decisions. Patients who are eligible for the Medicare hospice benefit but do not elect hospice have increased incidence of hospitalization, worsening care, unneeded acute interventions, and additional costs in quality of life and Medicare funding.

i. Definition of palliative dialysis

Palliative dialysis may be defined as dialysis for kidney failure in which the primary focus is symptom relief and quality of life. This approach is intended for patients with kidney failure whose goals are not aligned with a standard life-prolonging approach to dialysis, similar in scope to the current hospice benefit under Medicare.

ii. Beneficiary eligibility and targeting

KCP supports appropriately broad eligibility criteria for patients seeking palliative dialysis, driven by patient goals and values, not solely a diagnosis or prognosis. We would suggest eligibility criteria consistent with Medicare hospice eligibility, including a physician referral for dialysis as a hospice patient, along with a certified prognosis of a remaining life expectancy of 6 months or less at the time of eligibility.

iii. Payment policy considerations

With respect to the payment structure, KCP supports a program in which payment for palliative dialysis is reimbursed directly to dialysis providers. This system will facilitate consistent payment considerations for palliative dialysis and continuity of care for patients with ESRD to support a smooth transition to end-of-life care.

c. RFIs on Potential Payment Changes to Support Alternative Dialysis Schedules

Although KCP supports CMS' consideration of methods to support alternative dialysis schedules, we have serious concerns with the Agency's discussion of wholesale payment changes to the ESRD PPS. Moving from a per-treatment payment framework, to a per-month or per-day payment system, creates significant risks and costs of transition, while failing to provide an effective framework for alternative dialysis schedules. In effect, this proposal is even less

patient-centered than the current ESRD PPS bundled payment system, and it fails to reduce any administrative burden when considering alternative dialysis schedules. By effectively mirroring the current payment methodology for PD, it is unclear that this proposal would incentivize the use of more PD.

When CMS considered alternative units of payment during the initial design of the ESRD PPS, the Agency rejected this monthly payment design for economic and administrative reasons. Those same downsides exist now, even more so because the treatment and reimbursement ecosystem has been built on the current per-treatment system. At the time, CMS expressed concern with administrative issues caused by patient interruptions of care in a month, due to hospitalization, facility switching, or other interruptions. CMS was also concerned that economic incentives under a monthly system might lead to missed treatments, since facilities would no longer lose payments if treatments were missed, or require high-burden administrative activities to track and ensure continued quality of care.

Our members have identified numerous potential downsides with such a proposal. Chief among them is that CMS discusses the proposal as a budget-neutral alternative to the current payment approach, capping payment for alternative modalities or schedules at current levels – rather than being able to provide payments to incentivize and account for alternative patient treatment options and patient-centered care delivery. Without an overall increase in funding, KCP does not believe dialysis treatment providers could take on the additional burden of managing alternative treatment methods and schedules.

Lastly, consistent with the 4-year transition required to move from the composite system to the ESRD PPS, a payment shift of this magnitude would implicate very significant administrative costs, risks to patients and providers during the transition, and a need for years of advanced planning and consideration to avoid interruption to necessary dialysis care. Providers have entered into contracts with commercial payors and Medicare Advantage plans to govern payment rates and methodology, all of which are based on current funding mechanisms. Shifting the terms and conditions of those contracts will require a significant investment of time and resources to develop alternative payment models and mechanisms – and then design and negotiate new contracts. This new payment framework would also need to redesign the TDAPA, TPNIES, and outlier payment mechanisms (among others), all of which are necessary to facilitate access to new therapies and resource-intensive patients. We believe this proposal does not simplify payment mechanisms – it would complicate them, in a way that would further risk access to care rather than facilitate new patient-centered delivery schedules.

KCP does not support further consideration of moving the ESRD PPS from a per-treatment payment framework to a per-month or per-day payment system and urges CMS not to consider these policy proposals for future development. If CMS does continue to consider fundamental changes in payment methodology, KCP strongly urges the Agency to convene a TEP to discuss payment reform that aligns with the best interest of patients, which could also address CMS' interest in facilitating reasonable and achievable alternative dialysis schedules.