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August 29, 2025

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

Dear Administrator Oz,

The National Kidney Foundation is pleased to submit comments on the Calendar Year (CY) 2026 ESRD Prospective Payment System. This letter includes comments that are in-scope and out of scope. Our purpose is to both respond to the immediate provisions of the proposed rule for CY2026 while noting areas where the PPS could be modernized, understanding that many of the reforms to the PPS that are needed require new Congressional authority.

The ESRD bundle and the ESRD Quality Incentive Program (QIP) are now over ten years old. The ESRD Conditions for Coverage have only been updated once since 1976. It has been more than fifteen years since the last update. Meanwhile, traditional Medicare covers a decreasing proportion of ESRD beneficiaries each year. A new vision for ESRD payment and quality is needed to keep pace with changes to coverage, advances in technology, and new opportunities to advance care delivery.

NKF is sensitive to the context in which the ESRD bundle operates. The dynamic in which the federal government is overbilled for products and services has not changed since dialysis companies settled lawsuits related to billing for more Epoetin, a drug that stimulates the production of red blood cells used to treat anemia, than was administered in 2012 and 2013. Only recently, CMS took steps to tighten coverage criteria for skin substitutes and tissue-based products to address ballooning Part B expenditures for these products. As HHS Secretary Robert F. Kennedy has noted, fraud, waste, and abuse drive up program expenditures while leaving fewer resources for patients who rely on the Medicare program. Any future oriented vision for the ESRD program will acknowledge CMS' interest in and an obligation to steward the Medicare Trust Funds and ensure resources are used in an evidence-backed manner.

The ESRD Bundle: Challenges & Opportunities

The ESRD bundle has been both a successful and unsuccessful program. From the perspective of the overall stability of the Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) Trust Funds, inflation adjusted fee-for-service ESRD expenditures have consistently accounted for between 5 and 7.5 percent of total Medicare spending over the past decade.[1] Inflation adjusted per-person per-year spending on dialysis across Medicare only, dual eligible, and Medicare Advantage (MA) beneficiaries has either been consistent or has fallen since 2012.[2] CMS has achieved this while operationalizing add-on payment adjustments for services inadequately accounted for by Composite Rate Services, including the

[1] https://usrds-adr.niddk.nih.gov/2024/end-stage-renal-disease/9-healthcare-expenditures-for-persons-with-esrd
[2] Ibid.

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Transitional Drug Add-on Payment Adjustment (TDAPA), the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES), a transitional pediatric ESRD add-on payment adjustment (TPEAPA), a post-TDAPA add-on payment adjustment to support adoption of new injectable, intravenous, or oral drugs and biologics at the conclusion of the TDAPA period, and an add-on payment for home and self-care dialysis.

On some dimensions, ESRD care for patients has improved. While the bundled payment system is not directly attributable to the improvements we describe here, it is notable that ESRD care has overall improved on some indicators while CMS has held per-patient costs steady in the fee-for-service program. All-cause mortality in all adult ESRD patients, ESRD patients using HD, and ESRD patients using PD decreased between 2010 and 2019.[3] Meanwhile, access to home dialysis has increased after falling precipitously from a peak of approximately 40 percent of ESRD patients using home modalities in the mid-1970s.[4] [5] Since 2012, the percentage of new dialysis patients using home modalities has increased more than 70 percent, from 8.5% to 14.5%. Home dialysis among prevalent patients has also grown since 2012, although more slowly. Critically, access to home modalities has grown while the complications associated with home dialysis have fallen. The US Renal Data System (USRDS) finds that hospitalizations for peritonitis and vascular access infections have steadily declined since 2012.[6]

Kidney transplantation has also increased.[7] Multiple interventions targeted at increasing kidney transplant waitlisting have been implemented over the years with limited results, although the number of candidates added to the waitlist in 2023 was the highest number in a decade.[8] CMS has tested three demonstrations of kidney care delivery innovations, two of which made or are making demonstrable improvements in ESRD care. The End-Stage Renal Disease Seamless Care Organization (ESCO) Model demonstrated that a coordinated care design around dialysis could reduce Medicare spending, hospital utilization and readmission, and improve dialysis adherence and some dialysis quality measures.[9] The Kidney Care Choices (KCC) Model is showing early promise at improving optimal starts and increasing access to home modalities, among other important indicators of high quality care for individuals with late stage CKD such as preemptive waitlisting.[10]

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[3] *Ibid.*

[4] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

[5] Blagg CK. A Brief History of Home Hemodialysis. *Advances in Renal Replacement Therapy*. 1996;3(2):99-105. doi:10.1016/S1073-4449(96)80048-3

[6] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

[7] https://srtr.transplant.hrsa.gov/ADR/Chapter?name=Kidney&year=2023

[8] *Ibid.*

[9] https://www.cms.gov/priorities/innovation/data-and-reports/2022/cec-annrpt-py5-fg

[10] https://www.cms.gov/priorities/innovation/data-and-reports/2025/kcc-2nd-annual-report-preview

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Challenges related to the bundle persist. From a dialysis market perspective, the ESRD bundle is a driver of mergers and acquisitions that have led to significant market consolidation.[11] The two largest dialysis organizations own more than 70 percent of the market with resulting impacts on dialysis prices, particularly for commercial insurers, efficiency, and patient access.[12] The bundle has not kept pace with inflation. Highly efficient LDO facilities can withstand these pressures on their margins, but low-volume facilities, many of which operate in rural areas, cannot. MedPAC's finding that the lowest treatment-volume facilities have a −19.0% Medicare margin exemplifies this point.[13]

While home dialysis has grown, it has not achieved the target set by the Advancing American Kidney Health initiative of 80% of the ESRD population using a home dialysis or being transplanted nor approached a more modest goal of 25 percent home dialysis utilization to align with other comparable nations like Canada, Australia and New Zealand, and some Scandinavian countries.[14] [15] [16] Most of the growth in home dialysis is from peritoneal dialysis (PD) while home hemodialysis (HHD) has not grown as quickly. The reasons for this are anecdotal and likely multifactorial, including HHD programs being more difficult to implement and scale, patient fear of self-cannulation patients, and vertical integration among dialysis companies and dialysis machine manufacturers that may limit patient choice.

Among US dialysis patients, differences in home dialysis access persist. More White and Asian patients are accessing peritoneal dialysis (PD) whereas in-center dialysis continues to be more common among Hispanic and Black patients.[17] The reasons for unequal access have been well characterized and involve patient-level factors like delayed referral to nephrology care, dialysis-facility factors like provider bias, and system-level factors like the lack of staff support once a patient has transitioned to home.[18]

Finally, as we note further on in this letter, we believe it is time to consider significant refinements to the policies for incorporating new drugs and technologies into the PPS. As CMS is aware, studies demonstrate that bundling drugs into the PPS causes utilization to decrease.[19] While we appreciate the intent of the

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[11] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch5_MedPAC_Report_To_Congress_SEC.pdf?utm_source=chatgpt.com

[12] Erickson KF, Eck C. Considering the Effects of a Recent US Supreme Court's Ruling on Dialysis Care Costs. *Clinical Therapeutics*. 2023;45(3):272-276. doi:10.1016/j.clinthera.2023.01.015

[13] https://www.medpac.gov/document/july-2025-data-book-health-care-spending-and-the-medicare-program/

[14] Damasiewicz MJ, Polkinghorne KR. Global Dialysis Perspective: Australia. *Kidney360*. 2020;1(1):48-51. doi:10.34067/KID.0000112019

[15] Borkum M, Bevilacqua M, Romann A, et al. A Province-Wide Home Dialysis Program Review: Challenges, Strengths, and Future Strategies. *Can J Kidney Health Dis*. 2025;12:20543581251324560. doi:10.1177/20543581251324560

[16] Lundström UH, Meeus G, Aronsen T, et al. Increasing the adoption of home dialysis through improved advanced kidney care patient education: a call for action. *Clinical Kidney Journal*. 2025;18(4):sfaf087. doi:10.1093/ckj/sfaf087

[17] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

[18] Rivara MB, Mehrotra R. The changing landscape of home dialysis in the United States: *Current Opinion in Nephrology and Hypertension*. 2014;23(6):586-591. doi:10.1097/MNH.0000000000000066

[19] Karaboyas A, Zhao J, Ma J, et al. Incorporation of Calcimimetics into End-Stage Kidney Disease Bundle: Changes in Etelcalcetide Utilization and Parathyroid Hormone Control following End of Transitional Drug Add-On Payment Adjustment Designation. *CJASN*. 2025;20(2):218-228. doi:10.2215/CJN.0000000583

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TDAPA and TPNIES policies and believe there are dimensions on which these policies have succeeded, we continue to be concerned by reports that patients face extra burden in accessing the products that they need. Only one hemodialysis machine has secured approval for payment under the Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) in six years although four dialysis machines have been cleared through FDA's 510(k) pathway during that same period (Quanta Dialysis System, VersiHD with GuideMe Software and two clearances for the Fresenius 5008X CAREsystem). We are also uncertain about the extent to which the TDAPA and TPNIES policies can accommodate technologies like wearables, remote-patient monitoring, the wearable or implantable kidney, and technologies and devices to support cannulation. We believe the time is right to revisit these policy frameworks.

B. Proposed Provisions of the CY 2026 ESRD PPS

1. Proposed CY 2026 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

NKF does not have specific comments on the proposed CY2026 ESRD market basket update, update, productivity adjustment, and ESRD labor related share beyond noting that CMS should have the authority to implement a more nuanced process for accounting for inflation. We agree with other stakeholders that updates to the base rate since the COVID-19 pandemic have not adequately captured 2021 and 2022 inflation. Prices remain high compared to pre-pandemic levels, even as they have moderated somewhat from their peak during the pandemic.

As CMS is aware, staffing costs are one of the highest operational costs associated with delivering dialysis. Dialysis facility staffing is enormously important to how patients experience dialysis. A facility with well-trained, confident, compassionate staff can be the difference between a patient feeling safe or not safe, heard or not heard, able to raise concerns or remain quiet for fear of retaliation, successfully transition to home dialysis, and/or secure a place on the kidney transplant waitlist with the goal of remaining active on the list, being successful with treatment, and receiving a kidney transplant.

While we support a labor related share of 55.2 percent, we note that facilities continue to struggle to hire and retain staff, with implications for the patient experience, particularly the ability of patients who express an interest in home dialysis to be able to train for it and move home in a timely fashion. Ultimately, we understand that CMS' process is to consider updates to the labor-related share when the ESRD bundle is rebased, as it last was in 2019. At that time, CMS raised the labor-related portion of the base rate to 55.2% where it remains. Since the wage index policy is subject to budget neutrality, the only mechanism available to CMS to account for what we understand to be the increasing proportion of the price inputs devoted to staffing would be to consider updating the base year for the ESRDB market basket. CMS continues to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule.

2. Proposed CY 2026 ESRD PPS Wage Indices

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NKF does not have specific comments on the ESRD PPS wage indices. We wish to offer our continued thanks to CMS for its attention to the matter of creating an ESRD specific wage index, which was finalized in the CY2025 ESRD Prospective Payment System (PPS) final rule. Overall, we believe CMS has been a steadfast partner in implementing Section 1881(b)(14)(D)(iv)(II) of the Act, which authorizes CMS to account for variation in wages based on geography. The PPS was first implemented with a wage index based on hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS) and ultimately refined in response to feedback from stakeholders including NKF that hospital wage data does not reflect ESRD staffing costs. We appreciate CMS' responsiveness. CMS has also implemented thoughtful policies to handle changes in the Office of Management and Budget (OMB)'s designations of urban and rural areas and areas with very low wages (i.e., Puerto Rico and the U.S. Virgin Islands). As we do not expect staffing shortages to improve in the near term and as noted above, we support CMS' ability to implement a nimbler process for accounting for system-wide fluctuations in the prices of labor.

3. Proposed CY 2026 Update to the Outlier Policy

NKF reiterates our longstanding comment that while we support the outlier policy to protect patients that incur especially high costs, the policy continues to have the unintended consequence of withholding money from facilities that could otherwise be reinvested to support patient care. Over the years, CMS has acted in good faith to improve the methodology to target 1% of total Medicare payments with the result that CMS reports payments represented approximately 0.8 percent of total payments, which is slightly below the 1.0 percent target based on preliminary 2024 claims. In general, we reiterate a comment we have made in previous years that while it may be practical and we understand that drugs and biologics are included in the definition of Composite Rate Services, we would appreciate the opportunity to work with CMS to consider whether the outlier policy is the appropriate means to reimburse for high-cost ESRD outlier drugs and biological products and the case- mix adjusted post-TDAPA add-on payment adjustment and the extent to which the outlier policy is crowded out by drugs and biologics at the expense of other Composite Rate Services.

4. Proposed Impacts to the CY 2026 ESRD PPS Base Rate

NKF supports the proposed ESRD PPS base rate for CY 2026 of $281.06. The National Kidney Foundation (NKF) generally agrees with the Medicare Payment Advisory Commission (MedPAC) that for most facilities, dialysis payment is adequate as measured by dialysis facility capacity and number of ESRD beneficiaries in need of dialysis. Although the profit margin associated with treating traditional Medicare beneficiaries is low, analysts forecast that large dialysis company revenue is projected to grow due to the relatively steady need for dialysis services.[20] [21] [22]

[20] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_MedPAC_Report_To_Congress_SEC-1.pdf

[21] https://freseniusmedicalcare.com/en/media/newsroom/q2-2025/

[22] https://investors.davita.com/2025-08-05-DaVita-Inc-2nd-Quarter-2025-Results

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Although we generally believe the base rate is adequate, NKF does not believe the payment for incorporating new drugs and devices into the PPS is. We have concerns that the policy of amortizing the cost of TDAPA and TPNIES products across all dialysis treatments, while largely methodologically sound, does not sufficiently support patient access and advantages LDO clinics, among other unintended consequences. While we understand CMS is committed to the policies it has established and finalized over numerous years of rulemaking, we are eager to look ahead and consider whether a different policy framework can better support patient needs.

6. Proposed Post-TDAPA Add-On Payment Adjustment Updates

NKF understands the policy & methodology applied to the post-TDAPA add-on payment adjustment, but we note that the policy is not meeting the needs of non-LDO dialysis organizations. An example relating to Korsuva from an NKF volunteer who runs an independent dialysis facility in Mississippi follows:

"My cost is $1800/case (12 vials/65 mcg/vial) = $150/vial. 1 vial = 1 dose for anyone who weighs less than 120 kg (we have a few that weigh more). The usual dose around 45 mcg. The post-TDAPA payment for Korsuva would be .263 cents per .1 mcg or or $118.49 for 45 mcg. We are not reimbursed for the 20 mcg we did not use (single-use vial). That is a ***loss*** *of $31.51 per dose, or $409.63 per month, or $4,915.56 per year per patient. We also lose the cost of syringes/disposables and nursing time dedicated to administration."*

7. Proposed Changes to the TDAPA Eligibility Criteria

NKF supports the proposal to modify the language of § 413.234 to reflect that a TDAPA application must be submitted within 3 years of FDA approval for a new renal dialysis drug or biological product to be eligible for the TDAPA.

8. Proposed Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Territories

NKF supports the proposal to create a new facility-level payment adjustment for ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories. We appreciate CMS' responsiveness to the request and its diligence in determining that facilities in these areas have higher non-labor costs when compared to ESRD facilities in the contiguous U.S. We hope that the facility-level payment adjustment will support access for patients living in Alaska, Hawaii, and the U.S. Pacific Territories.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

We continue to have concerns that, as designed, the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) is not working as CMS intended. From CMS' standpoint, it is rational to use the same substantial clinical improvement standard as CMS does in the Inpatient Prospective Payment System (IPPS) through the new technology add-on payment (NTAP). We also

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understand and agree that patients deserve better than a "me too" drug or device that offers incremental benefits over existing technology.

Innovation is often an incremental process. NTAP approvals have grown in the past five years, driven by drugs like CAR-T therapy, which can result in remissions of certain cancers. The availability of these clinically meaningful innovations is the result of over 30 years of science, funded by a mix of public investment and proprietary research and development. No such pipeline has ever existed in kidney disease. One study estimated that the National Institutes of Health (NIH) spent $29 per kidney patient per year compared to $568 per cancer patient per year.[23] In Fiscal Year 2024, the National Cancer Institute (NCI) received approximately $7.2 billion, compared to $2.3 billion for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), of which only portion went to nephrology research.

We believe it may be time to consider whether, given the very different research and development environment for dialysis, as well as the additional complexity in achieving substantial clinical improvement in the dialysis population given the high level of morbidity and mortality, refinements to the policy are warranted. We would be pleased to collaborate with CMS to find ways to bring much needed new technology to people who rely on dialysis.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2026

As we note elsewhere in this letter, NKF is concerned that the tradeoffs of the TDAPA policy have begun to outweigh its benefits. We understand the rationale for the policy and appreciate the work CMS continues to do to operationalize TDAPA and create a runway to support and streamline adoption. Our general concern is that a policy that amortizes costs across all dialysis treatments provided, while efficient, has not successfully dealt with the impact on the variable constraints that impact patient access. In other words, like other aspects of the bundle, the policy has successfully incentivized efficiency with some consequences for the individualized patient experience. We believe, in general, it is time to grapple with and resolve those consequences.

With regards to two new renal dialysis drugs for which the TDAPA payment period would continue in CY 2026 (DefenCath® (taurolidine and heparin sodium) and Vafseo® (vadadustat), several examples from the committee of patients and professionals that inform NKF's positions on key policies like TDAPA follow:

"I can rarely get new drugs immediately through my pharmacy (e.g., DefenCath and Vafseo). Pharmaceutical companies ensure LDO access first. I have to contract with the distributor, and this takes a long time. I cannot buy drugs that require an 'authorized specialty pharmacy (Vafseo).'" -Dialysis facility administrator

[23] Mendu ML, Erickson KF, Hostetter TH, et al. Federal Funding for Kidney Disease Research: A Missed Opportunity. *Am J Public Health*. 2016;106(3):406-407. doi:10.2105/AJPH.2015.303009

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"In general, my pharmacy is great at keeping costs low [but] ASP overrepresents LDO buying power and underrepresents that of small/independent facilities." -Dialysis facility administrator

"Being put back on dialysis for the second time, I knew one thing for certain…I would never get a fistula or graft. I was ecstatic to learn of a new product, DefenCath, while at ASN in San Diego in 2024. This antimicrobial combined with heparin would reduce the risk of infection, which is of course a concern for patients with a CVC. I began reaching out to [a Large Dialysis Organization] in October of 2024 to urge them to help protect patients like me who have a CVC. I also reached out to Cormedix, the manufacturer, to ask what they could do from their end to push this along. As the months passed, although I was determined, I was also disheartened that this process was taking so long. [The LDO] (and all providers) are there to help heal and protect patients. Yet here I was, pleading with them to approve a drug developed for precisely that reason, with no luck. My frustration arrived to point where I was looking at other clinics in the area that carried DefenCath, regardless of the distance. Finally, 10 months after I first began fighting to get DefenCath into [LDO] clinics, I was able to use it for the first time on August 25th." – ESRD Patient, Louisiana

IV. Proposed Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The National Kidney Foundation (NKF) has been involved with the ESRD QIP since its implementation. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, Public Law 110-275, Section 153(c)) authorizes the ESRD QIP requires that CMS include measures of anemia management and dialysis adequacy. NKF has been closely involved with the implementation of the QIP since then, particularly through National Kidney Foundation's Kidney Disease Quality Initiative Clinical Practice Guidelines (NKF–KDOQI). We most recently gathered an expert group for a 2022 Kidney Disease Outcomes Quality Initiative (KDOQI) Workshop on Patient-Centered Quality Measures for Dialysis Care. Among the recommendations from that workshop was a consensus-based recommendation that dialysis facilities report through the End-Stage Renal Disease Quality Reporting System (EQRS) on key data elements related to social risk.[24]

We implore CMS to not finalize its proposal to remove accountability for the Facility Commitment to Health Equity reporting measure, Screening for Social Drivers of Health reporting measure, and Screen Positive Rate for Social Drivers of Health reporting measure. These measures drive accountability for high-quality, patient-centered dialysis care for all patients. CMS provides the following rationale for its decision: "[w]e have concluded that the costs of the continued use of these measures in the ESRD QIP may outweigh the benefits to providers and patients." Like all public policies, careful analysis of costs and benefits to patients and providers is warranted. The ESRD QIP measure set has proliferated since 2011, from three measures to twelve. Even with updates finalized over the years removing measures from the core set, each QIP measure is now worth only a fraction of the total two percent of Medicare reimbursement at risk. A discussion about a parsimonious, clinically meaningful, patient-centered measure set is warranted. **We**

[24] Weiner DE, Delgado C, Flythe JE, et al. Patient-Centered Quality Measures for Dialysis Care: A Report of a Kidney Disease Outcomes Quality Initiative (KDOQI) Scientific Workshop Sponsored by the National Kidney Foundation. *American Journal of Kidney Diseases*. 2024;83(5):636-647. doi:10.1053/j.ajkd.2023.09.015

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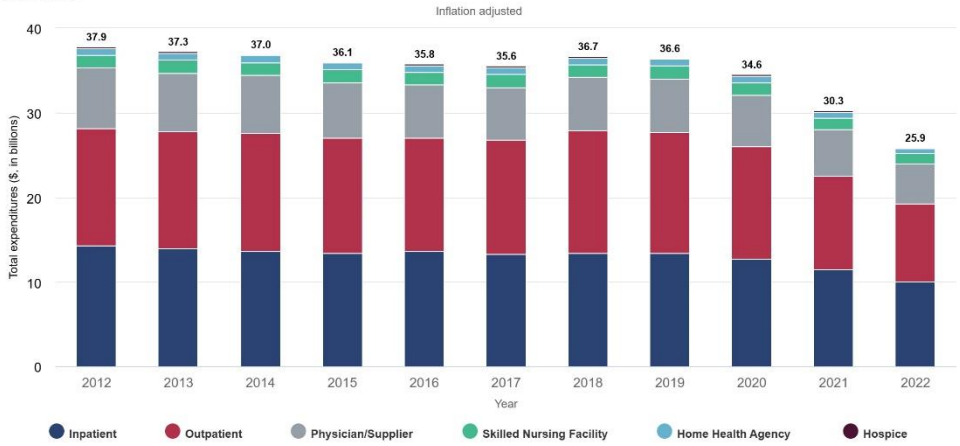
respectfully request CMS pause its proposal to remove the Facility Commitment to Health Equity, Screening for Social Drivers of Health, and Screen Positive Rate for Social Drivers of Health reporting measures until the time that a discussion across the community can be convened. We also note that while fee-for-service spending on inpatient and outpatient services ESRD beneficiaries are similar, inpatient utilization is the largest proportion of Medicare spending on ESRD (See Figure 9.5, in 2022, 10% inpatient, 9.3% outpatient). Social drivers like lack of reliable transportation, underemployment, financial strain, housing insecurity contribute to missed dialysis treatments, a major driver of hospitalizations, emergency department visits, and admissions to the intensive care unit.[25] CMS has an interest in ensuring there is some system-level accountability for dialysis facilities to address modifiable utilization that drives unnecessary spending.

Figure 9.5 Total Medicare fee-for-service Parts A and B spending for beneficiaries with ESRD, by type of service, 2012-2022[26]



Data Source: 2024 United States Renal Data System Annual Data Report

NKF supports the proposal to update the ICH CAHPS clinical measure to 39 questions. We appreciate CMS' efforts in addressing longstanding concerns that the length of the ICH CAHPS survey is contributing to patient survey fatigue. We are glad to hear that CMS is exploring a web version of the survey, as well as a version of the CAHPS survey that would address experience of care specifically for patients on home modalities. We would be delighted to support CMS in these efforts.

Opportunities To Improve Patient Centricity

The National Kidney Foundation (NKF) is eager to partner with CMS to shape the evolution of the ESRD QIP into a program that better centers the patient experience on dialysis, in terms of outcomes related to

[25] Chan KE, Thadhani RI, Maddux FW. Adherence Barriers to Chronic Dialysis in the United States. *Journal of the American Society of Nephrology*. 2014;25(11):2642-2648. doi:10.1681/ASN.2013111160

[26] United States Renal Data System. 2024 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2024.

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dialysis treatment that matter to patients and their psychosocial experiences that influence and are influenced by dialysis. The 2022 KDOQI workshop identified several recommendations for a "Dialysis Quality Program 2.0," including the addition of more meaningful patient-reported measures, individualization of metrics that target life goals, a uniform and basic level of education, and more opportunities for shared decision-making.[27]

Much ink has been spilled over the tradeoffs of the Kt/V dialysis adequacy measures. From CMS' perspective, the four dialysis adequacy clinical measures, or "topics," are guideline concordant, aligning with the KDOQI Clinical Practice Guidelines for Hemodialysis Adequacy and the 2012 KDIGO Clinical Practice Guideline for the Management of CKD. CMS has acted judiciously to respond to feedback from organizations like NKF that opposed the pooled dialysis adequacy measures and recommended modality specific targets, including those that account for residual renal function. We thank CMS for its efforts to evolve measurement of dialysis adequacy and understand CMS' constraints and the reasons, beyond statute, for creating a performance floor for dialysis adequacy.

Our concern, echoed by many other organizations, is that the system's fixation with Kt/V has reduced emphasis on a patient's health status, measures domains of Health-Related Quality of Life (HRQoL) like physical, mental, and social health that define how an individual feels and feels in their life and that are directly impacted by aspects of the dialysis treatment and the quality of care provided by the facility. For example, the Standardized Outcomes in Nephrology (SONG) initiative finds that fatigue is a core outcome for patients on hemodialysis.[28] Despite its importance to patients, no regulatory accountability exists. Patients have frequently noted the absence of focus on their overall quality of life while on dialysis. The ICH CAHPS measure is the only patient-reported outcome (PRO) measure in the QIP, and the lack of patient-centricity in its administration may outweigh the value of patient-reported experience of care given the limitations in response rate and actionability by the facilities and staff. Like the instrument often recommended for capturing the experience of patients on home modalities, Home Dialysis Care Experience (Home-DCE) instrument, a 26-item patient-reported experience measure, ICH CAHPS is a patient-reported experience measure (PREM) not a patient-reported outcome measure (PROM). Though both are important, PROMs measure the outcomes of dialysis as directly reported by the patient and are therefore an important means of achieving a patient-centered dialysis model.

CMS' efforts to collect "time on machine" data on Medicare claims is a meaningful advance in evolving the dialysis payment model to account for length of dialysis treatments. According to the Dialysis Outcomes and Practice Patterns Study (DOPPS), the U.S. lags other developed nations (Japan, Europe, and Australia/New Zealand) in dialysis treatment times with important clinical implications of shorter treatment times, such as the association with mortality, intradialytic hypotension, and worse volume control.[29] Patients receiving shorter treatments report more fatigue after dialysis and lower HRQoL.

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[27] Weiner DE, Delgado C, Flythe JE, et al. Patient-Centered Quality Measures for Dialysis Care: A Report of a Kidney Disease Outcomes Quality Initiative (KDOQI) Scientific Workshop Sponsored by the National Kidney Foundation. *American Journal of Kidney Diseases*. 2024;83(5):636-647. doi:10.1053/j.ajkd.2023.09.015

[28] https://songinitiative.org/projects/song-hd/

[29] Saran R, Bragg-Gresham JL, Levin NW, et al. Longer treatment time and slower ultrafiltration in hemodialysis: Associations with reduced mortality in the DOPPS. *Kidney International*. 2006;69(7):1222-1228. doi:10.1038/sj.ki.5000186

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Conversely, longer sessions over four hours with slower ultrafiltration associated with less feeling of being "washed out" and increased ability to participate in daily activities.[30] We are looking forward to better understanding the extent to which the payment system may be able to better address treatment time and the impact different treatment schedules may have on core dialysis outcomes that are important to patients and their care partners.

We also believe there is more to do to address dialysis patient's psychosocial needs. Arguably, Medicare regulations already guarantee accountability. For example, the ESRD Conditions for Coverage (CfCs) at 42 CFR 494.100 Condition: Care at home and 42 CFR 494.90 require dialysis facilities to implement an outcomes-driven, comprehensive plan of care that addresses patient needs. The extent to which the plan of care is a patient-centered process that incentivizes focus on holistic care for people on dialysis is not known, although as longtime patient advocate Derek Forfang was known to say, "most people on dialysis could not tell you what is in their plan of care, nor the last time they were invited to attend a plan of care meeting."

CMS has taken important steps to improve psychosocial barriers like converting the Depression Screening and Follow-Up Reporting Measure" into a clinical measure and soliciting input from interested parties on further accountability for patient life goals. Social workers make heroic efforts to secure transportation to and from dialysis, labor that will become more important as Medicaid beneficiaries face greater barriers to securing and keeping their coverage. We appreciate CMS' efforts and look forward to future collaboration. As we note above, removing the social drivers reporting measures from the QIP is a step backwards in a patient-centered dialysis experience for all individuals with ESRD.

D. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

Request for Information on Well-being and Nutrition

Nutrition counseling and structured nutrition interventions like Medical Nutrition Therapy (MNT) are essential clinical interventions for kidney patients. The Medicare program recognizes the value of care from a Registered Dietician (RD) through several mechanisms. CMS should use its existing authorities to expand access to evidence-backed nutrition interventions for beneficiaries with kidney disease. Most importantly, in alignment with the Secretary's commitment to the grassroots Make America Healthy Again (MAHA) movement, the Secretary should act to expand access to MNT for beneficiaries with CKD. Other tactical recommendations are outlined in this section.

Depending on the stage of kidney disease, people with CKD need tailored nutrition support aimed at managing blood sugar and blood pressure, reducing cardiovascular risk, controlling levels of sodium, potassium, phosphorus, calcium, and achieving a protein balance that prevents malnutrition while also reducing protein load on the kidneys. Once a patient begins dialysis, protein needs increase, and

[30] Rayner HC, Zepel L, Fuller DS, et al. Recovery Time, Quality of Life, and Mortality in Hemodialysis Patients: The Dialysis Outcomes and Practice Patterns Study (DOPPS). *American Journal of Kidney Diseases*. 2014;64(1):86-94. doi:10.1053/j.ajkd.2014.01.014

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potassium and phosphorus are more restricted due to the risks of hyperkalemia and hyperphosphatemia, respectively. Key vitamins and minerals must be replaced due to losses over the course of dialysis treatments. Patients also must deal with fluid restrictions to prevent volume overload, reduce interdialytic weight gain, and avoid low sodium concentration in the blood.

For patients with CKD, Medicare covers six sessions with an RD to provide Medical Nutrition Therapy (MNT). MNT regulations are codified at 42 CFR 410.130 through 42 CFR 410.134. Beneficiaries with certain stages of CKD can access MNT when referred by physician. Despite the availability of MNT, utilization is low. Several solutions have been proposed to increase MNT utilization, many of which are not actionable by CMS without new legislation. However, there are steps the Secretary should take to expand access to this essential but underused benefit.

The authorizing statute for MNT is the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000. The statue provides wide latitude for eligibility for MNT, deferring to the Secretary to establish the criteria for eligibility "after consideration of protocols established by the dietician or nutrition professional organizations" (42 U.S.C. §1395x(s)(2)(V)). The most recent clinical practice guideline from the Kidney Disease Outcomes and Quality Initiative (KDOQI) and the Academy of Nutrition and Dietetics (AND), recommend that for adults with CKD stages 1 through 5, an RDN provide MNT with the goals of optimizing nutritional status, minimizing risks of comorbid conditions, alternations in metabolism, and adverse clinical outcomes.[31]

CMS could consider:

- Using the Secretary's authority to expand access to MNT for beneficiaries with all stages of CKD
- Codifying eligibility for MNT based on CKD stage rather than using the outdated term "chronic renal insufficiency. MNT regulations at 42 CFR 410.130 "Chronic renal insufficiency" tie eligibility to glomerular filtration rate [GFR] 15-59 ml/min/1.73m^2 rather than stage of CKD. Neither the National Kidney Foundation nor Kidney Disease Improving Global Outcomes (KDIGO), which produces clinical practice guidelines in nephrology uses the phrase "chronic renal insufficiency" to mean either CKD as defined by the KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of CKD, or CKD following a kidney transplant.

Request for Information on CKD Measures

The National Kidney Foundation (NKF) is the measure steward of Kidney Health Evaluation for Adults with Diabetes (KED), a core process screening measure driving guideline-concordant kidney disease testing in adults with diabetes. Over 35 million people are affected by CKD, and the majority are unaware. The linchpin of transforming CKD care begins with a uniquely simple solution: people at-risk and people who have documented evidence of kidney damage in their health record must be given this information and the health system must transform to enable them to protect their kidney health. Numerous positive outcomes

[31] https://www.ajkd.org/article/S0272-6386(20)30726-5/fulltext

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desired by every stakeholder flow from this simple solution. If we can prevent and treat kidney disease early, we will dramatically improve the health of the nation.

Kidney disease is detected and classified using two low-cost laboratory tests, estimated glomerular filtration rate (eGFR) and urine albumin-to-creatinine ratio (uACR). The KED measure, which is used in the Merit-Based Incentive Payment System (MIPS), the Healthcare Effectiveness Data and Information Set (HEDIS), and the Medicare Advantage Star Ratings, drives the performance of both tests in the population with diabetes, the cause of most kidney disease. We are working to incorporate hypertension into the denominator of the measure consistent with the latest hypertension clinical practice guideline from the American Heart Association and American College of Cardiology. [32]

NKF's Kidney Disease Improving Global Outcomes (KDOQI) is building on this foundational measure to define a core measure set for CKD. Measure concepts we are advancing include:

- Use of Novel Therapies among People with CKD and Diabetes
- Chronic Kidney Disease Diagnosis Measure Among High-Risk Populations
- Use of GFR and/or albuminuria to identify individuals with "rapidly progressing" CKD,
- Visits to nephrology among people diagnosed with late-stage CKD,
- Medical Nutrition Therapy (MNT)

We will follow up with CMS to share progress and next steps and to align on a path forward for defining and measuring excellent CKD care.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

The National Kidney Foundation (NKF) supports the termination of the ESRD Treatment Choices (ETC) Model. NKF has supported the ETC Model as a means of disrupting payment policy with the goal of shifting the environment towards home dialysis and kidney transplantation since the model's inception. We understand that for the purposes of the Innovation Center's evaluation that the model has not shown an impact on home dialysis access, transplant waitlisting or retention. As has been noted, politics and policy are downstream from culture. The impact of the Advancing American Kidney Health Initiative Executive Order (EO) signing, in which President Trump publicly committed to increasing access to home dialysis, is the type of unmeasured but meaningful incentive that may have contributed to shifts toward home modalities. NKF expresses its gratitude to the Innovation Center for pushing disruption to longstanding patterns of dialysis care forward.

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In summary, the National Kidney Foundation (NKF) expresses our thanks to CMS for working assiduously with the tools and authorities granted to it to improve care for people who rely on dialysis. We believe there

[32] Jones DW, Ferdinand KC, Taler SJ, et al. 2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA/SGIM Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *JACC*. Published online August 2025:S0735109725064800. doi:10.1016/j.jacc.2025.05.007

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is more to do to ensure the ESRD program can meet the need of every patient and family that relies on it while continuing to steward the taxpayer dollar. We look forward to partnering with CMS to advance this lifesaving and life enhancing work.

Sincerely,

Dr. Jesse Roach, MD
Senior Vice President, Government Relations
The National Kidney Foundation