



August 25, 2023

The Honorable Xavier Becerra
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 314G-01
200 Independence Avenue SW
Washington, DC 20201

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model [CMS-1782-P]

Dear Administrator Brooks-LaSure,

The National Kidney Foundation (NKF) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments on the Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model [CMS-1782-P]. NKF commends the Agency for its efforts to establish effective and efficient payment policies for Medicare beneficiaries living with kidney disease and values the alignment of comprehensive quality measures across federal programs to improve access to care and achieve health equity. NKF is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S.

Priorities for Improving the Patient Experience with Kidney Disease

"As a patient advocate, I visit numerous dialysis centers in the Midwest on a regular basis. Many home dialysis programs are hurting from lack of staff and patients interested in going home are not able to be trained. Consolidation of home dialysis facilities forces patients who want to achieve their best life with dialysis to drive long distance, or even worse, at times not be able to make the switch from in-center dialysis. When this happens, dialysis patient lives are in jeopardy." E. Ditschman, NKF Kidney Patient Advocate

The kidney care ecosystem, specifically the dialysis facility setting, is in dire need for global enhancements to improve care for all, and most notably, those from historically marginalized

populations. Real-world experience described above by a fervent patient advocate highlights that existing kidney care fails to meet expectations and is unable to produce hope for a better quality of life. Less than adequate healthcare coverage, inequitable clinical practices, decreased access to novel therapies and devices, and deficient patient education and awareness are only a few pervasive problems we aim to address and improve through the proposed policy changes to the bundled payment arrangements and quality measures outlined below. Our specific comments pertain to updates to the ESRD PPS for CY 2024 and proposed changes to the ESRD QIP for PY 2026 and PY 2027.

Comments on Proposed Updates to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for CY 2024

ESRD PPS Base Rate and AKI Dialysis Payment Rate

The proposed rule suggests an increase of the ESRD PPS base rate and the AKI Dialysis Payment Rate to \$269.99 (an increase of 1.6 percent) and finalizes a decision to forgo the application of a forecast error adjustment. The proposed rule further suggests the continued use of a labor-related share percentage of 55.2. NKF recognizes the considerable efforts of CMS to ensure resources for ESRD and AKI treatments, along with labor wages, are administered and utilized as efficiently as possible. We also recognize the concurrent inflationary pressures on facilities and would like to highlight the on-going tensions influencing decision-making and subsequently impacting patient care. Considering these concerns, we echo sentiments from stakeholders across the kidney care community that updates to the rates above fall below measured growth rates and have fueled the exodus of healthcare workers to other industries and early retirement.

We strongly encourage the alignment of ESRD PPS market basket updates with those in other Medicare provider settings, such as the Skilled Nursing Facility (SNF), the Inpatient Prospective Payment System (IPPS), the Outpatient Prospective Payment System (OPPS), and Home Health. These settings have received collective increases of approximately thirty percent since 2012. By one estimate, the use of lagged data in combination with the lasting effects of the COVID-19 public health emergency could reduce provider reimbursements by as much as 1 billion dollars through CY 2027. The magnitude of such compounded deficits calls for the application of an appropriate forecast error adjustment.

Further, NKF is gravely concerned about the dialysis facility closures across the country. Dialysis closures were uncommon in the past, but they are now frequent. One large provider closed 58 facilities in the final quarters of 2022, 53 facilities in 2023, and anticipates 100 additional facilities may be closed in the future. Another large dialysis organization with a significant market share has closed approximately 170 facilities within the last year due to on-going staffing shortages, supply chain disruptions, and increased costs resulting in economic constraints. These closures inevitably impact patient care and quality of life. Dialysis facility closures particularly impact Black patients, individuals

on Medicaid, and small facilities.¹ Closures are also associated with an increase in hospitalization rates within 180 days and suggestion of an increased risk of mortality.² Dialysis center closures lead to patients travelling longer distances to receive care or apply for placements in acute care settings. A 2023 study found that the median one-way increase in distance traveled was 6.6 miles (IQR, 0–20.5) in small-town/rural areas using now outdated data from 2001-2015.³ This leads to decreased quality of life for patients as they are making these trips at least 6 times a week.

Kidney patients and advocates have also raised the issue of dialysis facility closures and staff turnover rates over the last decade. In their experience, the loss of high-valued employees with specialized training has occurred because of low base rates. Employee churn negatively impacts the relationship established between patients and their care team. Staff members experiencing burnout have led to substandard quality of care and equity issues for certain sectors of the patient population. Reductions or complete elimination of the evening or 4th shift within dialysis facilities disproportionately impacts patients with limited work hour flexibility, leaving them with a fear of potential job loss. Physicians report an increased occurrence of prolonged hospitalization of patients due to the absence of available treatment slots within neighboring dialysis facilities.

Refinement to Low-Volume Payment Adjustment (LVPA)

The proposed rule states that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. NKF supports the proposed methodologies to establish multiple LVPA tiers or the establishment of a continuous function for increase and adjustments that aim to eliminate the “cliff-effect” for facilities furnishing less than 4,000 treatments annually to qualify for the current LVPA threshold. We additionally support proposed changes to the attestation process and facility closure allowances that provide flexibility during disasters and emergencies for geographically isolated ESRD facilities.

Kidney patients and advocates appreciate CMS’ commitment to address the issue of ESRD facilities’ ability to administer services during unusual circumstances. This is particularly important for patients driving up to two hours to receive treatments in rural areas of the country. Patients have reported specific experiences of interrupted treatment times due to inclement weather, such as roads not being cleared from a winter storm in time to allow travel to the 1st shift.

¹ Norouzi, S, Zhao, B, Awan, A, et al. Bundled Payment Reform and Dialysis Facility Closures in ESKD. *J Am Soc Nephrol.* 2020; 31(3): 579–590. doi: 10.1681/ASN.2019060575

² Niu, J, Saeed, M, Winkelmayer, W, et al. Patient Health Outcomes following Dialysis Facility Closures in the United States. *J Am Soc Nephrol.* 2021; 32(10): 2613–2621. doi: 10.1681/ASN.2021020244

³ Niu, J, Worsley, M, Rosales, O, et al. Facility Closures and Distance Traveled to Receive Dialysis Care in the United States. *Clin J Am Soc Nephrol.* 2023; doi: 10.2215/CJN.0000000000000274.

Unused and Discarded Amounts of Renal Dialysis Drugs and Biological Products

CMS aims to modify policies to more effectively identify and monitor billing and payment for discarded amounts of drugs. CMS proposes that in addition to the amount of a renal dialysis drug or biological product from a single dose container or single use package being reported, any discarded amounts would be billed using a JW modifier, and a JZ modifier would be used to indicate there was zero drug wasted or discarded. We agree with the need to better understand patient-specific costs associated with furnishing renal dialysis services to Medicare beneficiaries. We would also like to echo the sentiments of stakeholders across the kidney care community and advocate against the potential burden created by future claim denials in the absence of the JW or JZ modifier. Further, we believe more information on how this information may be used to inform future payment policy would be very beneficial.

New Add-on Payment for Drugs after Transitional Drug Add-on Payment Adjustment (TDAPA) Ends/Post-TDAPA

NKF applauds CMS' continued efforts to facilitate the adoption of innovative drugs into existing ESRD PPS functional categories. Kidney patients and advocates encourage CMS to implement solutions that protect patients' access to the appropriate drug of their choice. We echo the sentiments of stakeholders across the kidney care community that additional resources should follow the patient in circumstances when the ESRD PPS base rate is not modified and the outlier adjustment is inadequate. Concerns remain that a sudden decrease in payments after the end of the TDAPA period for new therapeutics could result in a decrease in access for these new renal dialysis drugs and biological products. In this spirit, we strongly suggest that the post-TDAPA payment adjustment that is applied to all ESRD PPS payments be extended past the current three-year proposed timeline and reflect the cost of the drug for patients that actually use the medication, as it does during the TDAPA period.

We also echo concerns across the kidney care community that the proposed post-TDAPA payment based on current utilization for difelikefalin for intravenous injection (Korsuva) during the TDAPA period may be inadequate and unintentionally contribute to patient access issues and decreased quality of life in the future. Difelikefalin was approved by the FDA for moderate to severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. Provider concern by a lack of clarity about post-TDAPA reimbursement may have depressed utilization of the drug. We encourage CMS to consider alternative solutions to address these concerns, such as an extension of the current difelikefalin TDAPA for an additional year to ensure the post-TDAPA policy captures an appropriate level of utilization.

"Time on Machine" Hemodialysis Treatment Data

The proposed rule states a requirement for patient-level reporting on resource use involved in furnishing hemodialysis treatment in-center in ESRD facilities would serve to apportion composite

rate costs for use in case-mix adjustments. NKF supports efforts to better understand the influence of race, ethnicity, comorbidities, and social determinants of health that influence equitable care administered within facilities. We agree that an accurate case mix adjustment could further ensure patient-centric care and also believe an implementation date of January 1, 2025 would allow proper time for facilities to make necessary adjustments for their record keeping and reporting systems. We echo concerns of other kidney care stakeholders that considerations should be given for resources expended on activities that take place once dialysis treatments are complete as part of any future model that will dictate payment. For example, patients receive medications such as certain antibiotics or other medications such as difelikefalin post-dialysis completion. Kidney patients and advocates also support this proposed change but would like to raise the concern of the potential for perceived or actual pressure on patients (and staff) to complete their full prescribed treatment time, especially in circumstances when patients benefit from shorter, more frequent dialysis treatments.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

NKF continues to support the TPNIES and appreciates CMS' sustained commitment for innovative pathways to approve new technologies, equipment, and supplies within the kidney disease and dialysis space, including home dialysis. Kidney patients and advocates recognize the rigorous criteria required for TPNIES approval aids in a credible and principled approval process, however, they also recognize the importance of minor technological improvements to existing therapies in lieu of great strides in clinical novelty and substantial clinical improvement (SCI). Small improvements in safety or pain management are appreciated and valued and speak to the nuances that differentiate ESRD from other disease states.

We echo sentiments of other stakeholders across the kidney care community that recommend small changes to the program to foster more applications and approvals, in addition to small changes that would create alignment with the TDAPA program. Specifically, we agree with and further amplify the following recommendations:

1. Extension of the TPNIES eligibility period to five years and implementation of a post-TPNIES payment adjustment

An extension of the TPNIES adjustment period from two years to five years would establish parity with the combination of current TDAPA and the proposed post-TDAPA payment adjustment. The current two-year time frame provision is an inadequate amount of time for organizations to adjust the scale of resources and infrastructure to support approved products/devices nationwide. A longer adjustment period is also necessary for companies to continue data analysis on a technology's safety and efficacy, real-time utilization rates, and claims approval/denial data shared with them by end-users in the medical community. This would also allow for a more impactful feedback loop and cooperation between CMS, manufacturers, and other third parties. Facilities must evaluate the

acquisition cost of new products against not only the price of others on the market, but also against the depreciation rate of what they currently use.

2. Extension of the TPNIES program by one year

Original projections during the institution of this program estimated that two years was enough time to “monitor the use and payments for the TPNIES to assess whether new and innovative machines are adopted by the ESRD facilities.” After 18 months of experience with TPNIES, key stakeholders have found a fair assessment based on monitoring of use and payment has been effectively hindered due to delayed claims payments. This has caused a ripple effect in which TPNIES has not facilitated adoption of new technology to the extent intended by the program, in large part due to the ineffective roll out of the program in its first year. In conjunction with our first recommendation, a one-year extension is needed to enhance implementation efforts. In the long term, an extension of the program to five years creates parity with current TDAPA and the post-TDAPA adjustment.

3. Improvement to the claims and reimbursement process

In the interest of good governance, we recommend CMS clarify how Medicare Administrative Contractors (MACs) will determine payment rates and process claims in order to support uptake, facilitate beneficiary access, and uphold the program’s intent. Stakeholders have experienced variable levels of awareness and knowledge about the TPNIES by the MACs, contributing to denials of submitted Capital Related Asset (CRA) TPNIES claims. Denied claims led to an administrative burden for ESRD facilities. We also encourage the development of more clearly defined payment parameters and rate settings. Specifically, we encourage the MACs to publish an online database that provides a discrete TPNIES payment amount, no later than March 31 of the first year of TPNIES eligibility.

Comments on Proposed Changes to the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2026

Removal of Ultrafiltration Rate Reporting Measure and the Standardized Fistula Rate Clinical Measure

NKF applauds CMS for their consideration of comments previously submitted regarding concerns for the use of vascular access measures within the QIP. We agree with the proposal to remove the Ultrafiltration Rate Reporting Measure from the QIP measure set under measure removal factor 2 (performance or improvement on a measure does not result in better or the intended patient outcomes) and the proposal to remove the Standardized Fistula Rate Clinical Measure from the QIP measure set under measure removal factor 3 (a measure no longer aligns with current clinical guidelines or practice). These changes will indeed help all ESRD patients achieve the “right” access for them and allow clinicians to support the best vascular access care in accordance with the Kidney

Disease Outcomes Quality Initiative (KDOQI) Vascular Access Clinical Practice Guideline 2019 Update and implementation tools.⁴⁻⁵

Kidney patients and advocates also support the proposed changes above and emphasize that the Long-Term Catheter Rate Clinical Measure should be retained, in agreement with CMS. Long-term catheter use may be the best option for dialysis treatment in some patients, particularly for those where placement of a permanent access is not technically possible or for those who are more mature in age when first beginning their treatment. Patients and advocates commend CMS for their efforts to ensure patients can maximize their choices and preferences.

Proposal to Adopt the Facility Commitment to Health Equity Attestation-Based Structural Reporting Measure

The proposed rule states the adoption of the Facility Commitment to Health Equity Attestation-Based Structural Reporting Measure will aid in accomplishing outlined goals and strategies within the CMS Equity Plan for Improving Quality in Medicare and aid dialysis facility leadership with setting specific, measurable, attainable, realistic, and time-based (SMART) goals to ensure equitable care is accessible to all. NKF supports this endeavor and the five commitment domains facilities are responsible for attesting to. We would like to highlight a concern regarding the absence of a measure requirement to take specific actions upon the analyses completed by facilities to address gaps identified.

Kidney patients and advocates also applaud this proposed change and suggest the installation of new health equity officers across dialysis organizations who should be charged with implementing effective changes based on these analyses. We would like to emphasize that while this important work may increase burden for smaller organizations in completing this requirement, we echo the findings of the CBE-convened Measure Applications Partnership (MAP) Health Equity Advisory Group review that caution the installation of a “checklist” measure that may not result in change at the systemic level. We further agree with the CBE-convened Measure Applications Partnership (MAP) Hospital Workgroup members that suggested a commitment to looking at outcomes of implemented changes. We thank CMS for transparency and support the public display of facility-specific results on an annual basis through the *Care Compare* website.

Modification to the COVID-19 Vaccination Coverage Among Healthcare Personnel Measure

NKF supports CMS’ proposal to modify the COVID-19 Vaccination Coverage Among Healthcare Personnel Measure to replace the term “complete vaccination course” with the term “up to date” in the vaccination definition and the inclusion of information on boosters and time frames. Kidney

⁴ Lok CE, Huber TS, Lee T, et al; KDOQI Vascular Access Guideline Work Group. KDOQI clinical practice guideline for vascular access: 2019 update. *Am J Kidney Dis.* 2020;75(4)(suppl 2):S1-S164. doi: 10.1053/j.ajkd.2019.12.001

⁵ https://www.kidney.org/professionals/guidelines/guidelines_commentaries/vascular-access

patients and advocates believe this component is an extremely important security measure for both patients and staff to remain safe during their time within the facility.

Conversion of the Clinical Depression Screening and Follow up Reporting Measure to a Clinical Measure

The proposed rule states the conversion of the Clinical Depression Screening and Follow up Reporting Measure to a clinical measure will help to ensure the measure is scored in alignment with current clinical guidelines for depression screening and follow up. We have previously commented on the importance of improving the mental health of dialysis patients, as depression is the most common psychiatric condition among patients with ESRD and may exacerbate the complications of ESRD, treatment adherence, hospitalizations, and mortality. While we have also previously advocated for a clinical measure, kidney patients and advocates have raised important concerns regarding the ability of the current clinical social workers in place to appropriately handle patients with these issues. Advocates do recognize they are well equipped to connect patients with established community resources, which is also very important. It has been reported that patients who do honestly report their feelings and are not adequately assisted may experience an extreme setback in their mental health. Advocates also fear patients may be pressured to complete the survey in order for facilities to achieve high completion rates due to the change in the reporting requirements. Another patient concern is the potential of a positive response to lead to stigma and impact their care negatively in the future. Also of great importance is the lack of privacy to engage with the care team to complete this survey if they are in need of assistance.

Comments on Proposed Changes to the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP) for PY 2027

Screening for Social Drivers of Health Reporting Measure and Screen Positive Rate for Social Drivers of Health Reporting Measure

The proposed rule states the screening of health-related social needs (HRSNs) is vital in addressing persistent disparities in patients with chronic conditions and will foster a meaningful and holistic collaboration between ESRD facilities, other healthcare providers, and community-based organizations. We agree and note that these two separate, yet complimentary measures will require the addition of more social workers within facilities, an important consideration in light of the concerns raised earlier within our comments on the ESRD PPS base rate and forecast errors as well as the exodus of staff from dialysis units, and may call for a potential need for changes to the Conditions for Coverage for End Stage Renal Disease Facilities. Kidney patients and advocates agree that significant resources are needed to address HRSNs and suggest that resources are offered to all patients in a blanket manner, without the need for annotation in the patient record that may negatively impact the patient's care experience in the future.

Supplemental Requisite Issues for Consideration

While outside of the scope of this proposed rule, NKF would like to provide comments on the plans for CMS to incorporate oral-only drugs into the ESRD Medicare payment bundle in January 2025. It is essential that proposed policies do not hinder innovation and development of new therapies. Further, proposed policies should ensure payment adequacy and allow for appropriate readiness of dialysis organizations to effectively operationalize in the instance of oral-only drugs being brought into the bundle. We are advocating for the exclusion of oral-only phosphate lowering therapies (PLTs) outside of the bundle. Any potential adjustment to the ESRD base rate would fail to alleviate concerns raised by stakeholders across in the kidney care community in the 2022 ESRD PPS Final Rule and the new Post-TDAPA Add-on Payment Adjustment discussed above for the 2023 ESRD PPS Proposed Rule would not apply to oral-only PLTs. Kidney patients and advocates have been very clear that they value patient choice and access to therapies approved during the shared-decision making process with their care team. We again urge CMS to carefully consider the aforementioned points, in addition to the pathophysiological limitations of therapy adherence during dialysis treatments.

NKF would like to augment the sentiments and legislative efforts of stakeholders across the kidney care community to expand the Medicare Kidney Disease Education Benefit to increase the personnel qualified to provide the education, allow the education to be administered within dialysis facilities, and expanding the benefit to Medicare beneficiaries diagnosed with CKD stages 3b through 5. These amended policies will aid in the increased utilization of this benefit by decreasing barriers and improving access through two important vehicles for underserved communities often impacted by worsened health disparities: cost and care setting. The elimination of the 20% coinsurance cost for Kidney Disease Education (KDE) for patients for whom it is prohibitive to accessing care is vital. The provision to administer this education within dialysis facilities is life-changing for patients who may have crashed onto dialysis and not have other options available or are regularly unable to get an appointment within an established nephrology practice by approved personnel. We recognize the importance of holding facilities accountable for inadequate efforts and encourage guardrails to prohibit “patient steering” and “marketing” with the use of branded materials.

Recent reductions in reimbursements for outpatient vascular procedures have raised concerns regarding patient access issues. Kidney patients and advocates have reported that forthcoming payment changes have the potential to intensify on-going geographic barriers to patients in rural settings who may have difficulty obtaining treatments due to facility closures. We call for CMS to further examine this issue.

The National Kidney Foundation again thanks CMS for the opportunity to provide comments on the CY 2024 ESRD PPS QIP Proposed Rule. Complimentary, innovative, and robust payment and quality policies are essential to the improved health outcomes for people living with kidney disease who deserve superior care within ESRD dialysis facilities. We welcome the prospect of providing additional insight and collaborating as a thought leader on future policy initiatives regarding these matters.



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Please contact Ivory Harding, Director of Quality and Regulatory Affairs, at Ivory.Harding@kidney.org with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to be "K. Longino".

Kevin Longino
CEO and Transplant Recipient

A handwritten signature in black ink, appearing to be "S. Rosas".

Sylvia Rosas, MD
President