KIDNEY CARE PARTNERS

August 22, 2025

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

Re: CMS-1830-P: 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,

On behalf of Kidney Care Partners (KCP), I want to thank the Trump Administration for providing the opportunity to submit comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model" Proposed Rule. We look forward to working with you and your team to achieve the vision of a healthcare system that is more transparent, efficient, and focused on improving the health and well-being of all Americans.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, 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 mission is to involve patient advocates, care professionals, providers and manufacturers to ensure:

- Individuals living with kidney diseases receive optimal care;
- Individuals living with kidney diseases are able to live quality lives;
- Dialysis care is readily accessible to all those in need; and
- Research and development lead to enhanced therapies and innovative products, which require sustainable reimbursement.

I. Overview of KCP's Alignment with the Administration's Agenda and Vision for CMS

The recommendations outlined in this letter align with your vision for CMS to shift the health care paradigm from focusing on the sick to fostering prevention, wellness, and chronic disease management. At its inception in 1972, the Medicare ESRD program sought

to provide Americans with kidney failure a way to manage this chronic condition through life-sustaining treatments (dialysis and kidney transplantation) that otherwise would be largely inaccessible to most Americans. As a result, any American with kidney failure has the opportunity to enroll in Medicare to access these treatment options.

However, the reliance on the federal government has grown disproportionately large, especially in the last several years as commercial insurers has pushed their enrollees to shift to Medicare primary coverage. The U.S. Renal Data System (USRDS) reports that since insurances began these practices, the percentage of patients relying on commercial coverage between 2012 and 2022 has fallen more than 36 percent.[1] KCP remains deeply troubled that the downward trend will only continue now that the Supreme Court has rewritten the Medicare Secondary Payer Act (MSPA) to allow insurers to eliminate coverage for treatments for kidney failure. As a result of being able to "dump" these patients into Medicare, commercial insurers have little incentive to provide the screening and preventative services that would slow the onset of kidney failure.

The Medicare ESRD Program has also lost sight of the patient as it has focused on indiscriminately cutting expenditures. The most prominent and recent example relates to a first of its kind treatment that the FDA awarded with breakthrough status and expedited review because of the serious nature of the condition and the urgent unmet medical need for an effective treatment options for patients. Yet, CMS finalized a policy that studies have shown has resulted in less than 1 percent of the individuals receiving dialysis with severe CKD-associated pruritis (CKD-aP) not being able to access the only FDA-approved therapy for the disease. As a result, these patients must endure the severe itching, infections, and other complications that reduce their quality of life and require the otherwise preventable use of antibiotics. While the final policy might save the ESRD program dollars, has led to poor health outcomes, missed dialysis sessions, greater depression, and additional barriers to obtaining a kidney transplant. We would like to work with you directly to find a balanced approach to this problem, such as that outlined in the Kidney Care Access Protection Act (KCAPA).

In addition, KCP is pleased that the Administration is requesting ideas about streamlining and leveraging technology solutions to improve information about patients and hold providers accountable for patient outcomes. KCP led the effort to adopt pay-for-performance programs in Medicare and even provided resources and expertise through the Kidney Care Quality Alliance to ensure the development and maintenance of meaningful measures. As described in the letter, KCP has been frustrated that community and patient-led recommendations to improve the multitude of ESRD quality programs have not been addressed. We hope that in working with you and your team we will be able to learn more about why CMS has not already adopted these recommendations and identify options for improving the program so that it better serves patients and providers, while meeting the goals you have outlined related to transparency and accountability.

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[1]USRDS. Annual Report. Figure 9.3a (2024).

KCP is excited to work with you to comprehensively reform the Medicare ESRD PPS so that it empowers patients to access solutions to better manage their chronic kidney disease and navigate the complexities of the health care system while also giving their providers access to better information and treatment options while holding them accountable for patient outcomes. Given your deep understanding of the need to incentivize and support innovative treatment options to drive meaningful improvement in patient outcomes and ultimately lower overall health care spending, we hope that you will partner with KCP so that those living with kidney disease are not left behind.

II. KCP urges CMS to reconsider the ESRD payment policy to better support patient access to innovation, address shortcomings of the market-basket, and support transplant.

The Medicare ESRD Program is broken. Patients who could have benefited from innovative therapies cannot access them because the payment system fails to adequately adjust the payment rate to account for such new therapies. Research and development for advancing treatment for patients with kidney failure is almost non-existent, while research and development in other disease states (including earlier stages of CKD not reimbursed under the ESRD PPS) have seen substantial treatment innovations. These innovations have led to improved patient outcomes and patient quality of life. For example in 2024, cancer care research received an estimated ten times more funding, and heart disease research 1.5 times more funding than kidney care research. Private innovative companies and investors are also unwilling to support even the most promising research in addressing kidney failure because Medicare fails to provide a sustainable reimbursement pathway if such innovations are developed. In the last 5 years, three of the most promising therapeutic advancements to improve patient outcomes have failed primarily due to CMS reimbursement policies.

The need for adequate adjustments to the payment rates remains critical because the current rates often do not cover the cost of providing the most basic care. As the latest MedPAC report demonstrates, facility margins, at best, are “break even” and often negative. Payment rates have essentially stagnated over time, despite government data showing that costs have risen significantly during the last 10 years. The substantial increases in the cost of labor, medical supplies, devices, and medications have consistently been higher than the inflation predicted by the ESRD market basket. This chronic underfunding has left patients with kidney failure behind and resulted in higher overall costs to the Medicare program and out-of-pocket expenses. More than 60 percent of individuals with kidney failure rely on the Medicare for their health insurance coverage. The program is not sustainable for patients unless it is significantly reformed.

As noted in Section I, KCP is excited that the Administration is committed to focusing on ways to prevent and better manage chronic diseases. With more than 35 million Americans living with kidney disease, we are committed to working with the Administration not only to address the root cause of kidney failure but also to support

those living with kidney failure to address the complex nature of the diseases. As part of that effort, we urge CMS to consider these core principles when developing policies for the ESRD PPS as well.

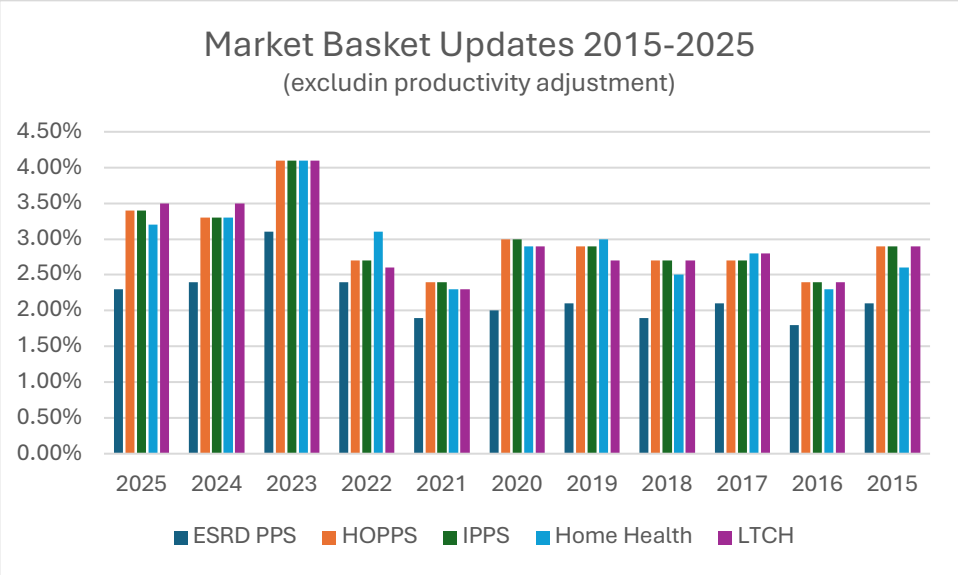
While KCP recognizes that these goals may not be accomplished in this, or any single, rulemaking effort, we urge the Administration to review the current ESRD PPS with fresh eyes and work with KCP to reform the ESRD PPS so that the payment system supports patient access to high quality care, empowers patient-centered decision-making, improves outcomes, promotes innovation to help end chronic kidney failure, and reduces overall (such as in Part A) Medicare spending. While our comment letter focuses on the proposals in this rule, we look forward to ongoing communications and conversations to truly transform the Medicare ESRD Program.

A. The ESRD Market-Basket Continues to Fail to Predict Actual Changes in the Cost of Providing Care to Individuals with Kidney Failure.

KCP remains deeply concerned that the ESRD market basket is flawed. We recognize that addressing only the short-comings of the market basket that Health Management Associates (HMA) experts have identified will not solve the systemic problems of the current payment system. As noted in Section I, KCP has undertaken a significant effort that includes organizations from across the kidney care spectrum to develop comprehensive system reform. Through this effort, we seek to modernize the payment system so that Americans with kidney failure have access to innovation and cutting-edge technologies that other individuals living with chronic diseases have; to support high quality, dedicated clinical staff with competitive salaries and benefits (which other Medicare providers can afford to provide under their payment systems); to empower patients with accurate and meaningful information to help them navigate the program as they manage their disease; and to improve access to kidney transplant and post-transplant services.

In last year's preamble to the final rule, CMS dismissed concerns that the ESRD market basket updates have been meaningfully lower for the last decade than those applied to other payment systems. While we appreciate the acknowledgment of our comments, KCP is concerned that CMS did not provide more specifics as to why it believes the data in dialysis facility cost reports differs so significantly from that in other provider cost reports as to result in ongoing differences in inflationary costs. We would also like to understand better why the preamble states that the price pressures for dialysis facilities are different than those facing similarly situated providers. It would be helpful to have a meaningful discussion so that if there are problems with the cost report data not reflecting actual costs, KCP could work with CMS to understand what costs CMS believes are missing from the dialysis cost reports. We would welcome the opportunity to work with CMS to share the price pressures facilities encounter and to provide specific information regarding itemized costs that are not reported or may not be transparent because they are incorporated into a broader category on the reports. It would be more productive to have a clearer explanation of CMS's interpretation of the data rather than to allow the problem to continue unresolved.

Despite the statements in the CY 2025 preamble, these differences are very real, continue to be significant, and have been consistent year over year, as demonstrated in Figure.[2]



According to HMA experts, the primary driver of these differences appears to be the fact that CMS has adopted a lower labor-related share for ESRD facilities. By comparison, the SNF-PPS, the labor-related share is 71.9 percent for 2026 and the Inpatient Hospitals PPS the labor-related share is 66 percent. We believe there needs to be a more current assessment of the role and cost of labor for dialysis services.

However, that is likely not the only problem with the market basket. As KCP highlighted in our letter for the CY 2025 ESRD PPS, there are a elements of the market basket that could be driving this difference as well. These include: the capital costs in the ESRD PPS being weighted significantly more than they are in other payment systems; the current market basket weighting two cost categories ("All Other Goods and Services" and "PPI - Final demand - Finished goods less foods and energy") significantly higher than similar categories in other payment systems.

We were disappointed that CMS dismissed these comments, writing that they "would likely not have had a significant impact on the past forecast errors." (Display Copy, pg. 33). This statement only addresses half of the problem. While the forecasts have been incorrect, even the actual market basket updates once calculated raise concerns. The forecast error adjustment that KCP continues to recommend is a short-term fix to address only part of the larger problem with the market basket.

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[2]CMS. "Market Basket Data." Available at: https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data (accessed April 2025).

CMS dismissed HMA's analysis related to the labor-related capital costs, writing that the "methodology of allocating a portion of the market basket capital cost weight to the labor-related share is consistent across the other CMS PPSs." (Display Copy, pg. 32) In terms of the concerns about the cost weight for "All Other Goods and Services," CMS wrote that "it appropriately reflects the cost distributions associated with providing ESRD services, as prescribed by law." (Display Copy, pg. 33). While we appreciate receiving responses to our comments, these responses do not address the HMA findings that the allocation of costs is in fact different. It would be helpful if CMS could explain why it believes these differences are appropriate given the under-performance of the market basket during the last decade. Moreover, the statute requires CMS to adopt a market basket, but left the details to the Secretary to determine. Thus, CMS has the authority to work with KCP and other experts, such as HMA, to fix this problem. HMA has identified that the impact of owning versus leasing facility space could be skewing the market basket calculations.

As we have noted in previous letters, a short-term fix to the more systemic problem with the current design of the ESRD market basket 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 at least the contractor's forecast does not result in dollars that are supposed to be directed at patient care are not lost from the system entirely.

We are puzzled by statements in the CY 2025 preamble that indicate that the forecast error since 2011 is less than 4.3 percent. This percentage is not consistent with the data CMS has included in the last several proposed and final rules. Table 1 shows the cumulative impact of the missed forecasts made by the contractor.[3]

Table 1. Base-Rate Update Math for ESRD-PPS 2025

MB Base Yearc	2016				2020			Cumulative
ESRD PPS Final Rule	2019	2020	2021	2022	2023	2024	2025	
Unadjusted Final MB Update	2.1	2.0	1.9	2.4	3.1	2.4	2.3	117.40%
Actual MB Inflation	2.3	1.9	2.9	5.1	4.1	3.3	3.2	125.10%
Final MB Update Compared to Actual (Forecast Error)	**-0.2**	**0.1**	**-1.0**	**-2.7**	**-1.0**	**-0.9**	**-0.9**	**-7.70%**

Based on the HMA analysis that relies upon the publicly available CMS data, the cumulative difference between the forecast and the actual increase in costs is nearly 8 percent. This

[3]Health Management Associates. Analysis of ESRD Market Basket Updates August 21, 2025).

table prepared by HMA reflects CMS's own publicly available data; it is not the community's interpretation or internal data. During the last five years, the methodology for calculating the inflationary costs for the ESRD PPS has failed to achieve its purpose. Ongoing monitoring only perpetuates the problem.

Without adequate funding, providers cannot provide the services that patients require. MedPAC's ongoing margins demonstrate the problem. We do not agree that the MedPAC "marginal profit" negates the plain meaning of the zero and negative Medicare margins that MedPAC has calculated during the last 10 years. While an interesting concept, the marginal profit analysis has several limitations. One such limitation is its reliance on outdated cost data which is particularly a problem given the challenges presented by data from 2020-2022. In addition, it does not accurately capture how providers actually make decisions about accepting Medicare patients. For example, adding a new patient to a shift has dramatically different costs if meeting that patient's needs can be absorbed into current staff or if new staff have to be added to support the patient. The marginal profit analysis also ignores the role of fix costs. It does not assess or comment on the appropriateness of the methodology to establish payment rates, but is a more general tool trying to understand provider incentives. Thus, we caution CMS on using it to evaluate Medicare payment adequacy.

To stop this continual loss of dollars from the ESRD payment system, KCP urges CMS to adopt the forecast error adjustment for CY 2026 that has been discussed during multiple rulemaking cycles. Specifically, we request that CMS adopt the forecast error and apply it retroactively to 2019. Any further delays would likely have a negative impact on patient access to high quality renal dialysis services. We also ask that CMS work with KCP to develop a comprehensive and sustainable reform to make sure that the Medicare ESRD PPS does not create a barrier to the Administration achieving its vision for individuals living with kidney disease.

B. The Substantial Volatility in the Wage Index Suggests Flaws in the Methodology.

KCP appreciates that for CY 2026, CMS recognizes that the proposed wage index values produce a net downward impact of nearly 0.9 percent on total payments calls for a corresponding upward adjustment to the base rate to preserve budget neutrality. We support maintaining an appropriate adjustment in the final rule to ensure changes in the wage index values between the proposed and final rule do not result in dollars being removed from the system.

While we recognize that the ESRD-specific wage index methodology is only in its second year, there is substantial variability in the values that suggest there is a flaw in the methodology. CMS data show that the wage index decreased dramatically for the substantial majority of ESRD areas. Seventy-two percent of the wage index areas experienced a decrease in the wage index value for 2026. This is a significant swing the

values that should cause CMS and the kidney care community to pause. While the significant changes in CY 2025 could have reflected the historic differences in the markets not captured by the IPPS wage index, that cannot be the reason for this second year of extreme variability. We are cognizant that the final rule may include even greater shifts when more recent data are applied.

This substantial variability suggests the more work needs to be done to support a more predictable and stable wage index policy. KCP recognizes that CMS may not be able to make methodological changes in this year's rule, so we ask that CMS commit to greater transparency and to working with KCP and our analyst to address the problem before the CY 2027 proposed rule is released. We realize that wage indices may not always be stable year-over-year because the lag in data and other factors. The IPPS wage index addresses these challenges in a number of ways, including allowing hospitals to reclassify their geographic designation to avoid substantial swings in the wage index value. CMS has appropriately adopted a cap for the ESRD wage index to help address the swings, but this policy alone does not protect against the swings that occurred in the first and second year of the index. In previous rulemaking preambles, CMS has highlighted a desire to provide payment predictability for providers. The current ESRD-specific index is not achieving that goal. It is important that CMS act to avoid a third year of such dramatic swings.

Finally, to provide for greater transparency, we ask CMS to provide the uncapped wage indices as well.

C. KCP Appreciates CMS Recognizing the Higher Costs Relate to Patient Care in Non-Contiguous Areas and Urges CMS Not to Apply the Adjustment in a Budget Neutral Manner.

KCP supports recognizing the higher costs in the non-contiguous areas identified in the proposed rule. However, addressing these historically under-reimbursed areas should not result in patients in the other parts of the United States having the rates for their services cut. With Medicare margins so narrow, a 40 cent reduction to the base rate is substantial and could result in more facilities experiencing a zero or negative Medicare margin. Just like the policies that apply to special payments for critical access hospitals, super-rural ambulance services, and the physician fee schedule 1.0 geographic practice cost index (GPCI) practice expense floor for frontier states, the non-contiguous areas payment adjustment (NAPA) adjustment should not be applied in a budget neutral manner. CMS has suggested that it applies a "longstanding philosophy" to implement adjustments for costs already included in the bundle in budget neutral manner (Proposed Rule, pg. 57; CY 2025 Final Rule, Display Copy, pg. 82). However, given the significant exception to this philosophy in other payment systems, we ask that CMS not finalize NAPA as budget neutral to be consistent in how it treats payment adjustments for other providers in these areas.

KCP is also concerned with the lack of transparency around the methodology and the potential for confounding factors that could skew the final analysis and final policy. For

example, HMA's analysis of the proposal highlights that the use of cost report data alone means that CMS has not assessed whether patient factors also play a role in the higher costs these facilities face. Moreover, the application of the trimming rules in such a small sample size could result in reduced statistical power, the loss of important data, and the distortion of the true distribution of costs because it is impossible to distinguish outliers from extreme observations with a small sample size. Given that the raw data suggests that costs in these areas may be as much as 30 to almost 50 percent higher than other parts of the United States, it is important to make sure the methodology reflects the actual costs in the adjustment to protect patient access to life-sustaining dialysis services in these areas. We ask CMS provide greater transparency and take into account additional data sources as it continues to apply NAPA in future years to ensure that the methodology is arriving at an appropriate adjustment amount.

D. KCP appreciates CMS's review of the outlier policy.

KCP remains supportive of the revised outlier policy methodology. Understandably, we are concerned that the 2024 outlier payments missed the target amount by paying out only 0.8 percent. HMA calculates that this percentage represents a leakage of about $0.63 per treatment. Interestingly, this underpayment is more than the per treatment cost of the NAPA adjustment CMS has proposed. CMS appears to assume that utilization will not change for CY 2026 and proposes outlier thresholds that are projected to pay out 1.87 percent of the bundle rather than 1 percent. The proposed rule findings suggest that trends in outlier services are declining more in 2025 and 2026 than the initial CMS data from 2021-2022 suggested in establishing the original 2024 outlier thresholds. We encourage CMS to provide updates on the policy's performance and to work with KCP prior to issuing the CY 2027 proposed rule to assess whether more specific modifications are needed to ensure that the outlier payments remain close to the 1 percent statutory target.

We also want to reiterate that the outlier policy is not a replacement for a policy ensuring that the base rate supports patient access to innovative products. The lack of patient access to Korsuva noted in Section I demonstrates the inadequacy of the outlier policy to be a permanent solution to this problem.

E. TDAPA Eligibility Criteria

While KCP agrees that TDAPA should apply to truly new products and generally supports providing a 3 year window in which a manufacturer could submit a TDAPA application, we encourage CMS to refine this timeframe. Specifically, we request that submission made within three years of FDA approval of a new ESRD indication for use as a dialysis drug or biologic product. In other words, if a manufacturer obtains a new FDA approval for a new ESRD indication, then the manufacturer should have three years from that new indication to apply for TDAPA. Given the lack of investor interest in supporting new renal dialysis-related drugs and biological products, we encourage CMS to avoid adopting another policy that will create more barriers to patients having access to

innovative therapies related to treating kidney failure. We agree that the implementation date for the proposed changes should not be before January 1, 2028.

Notwithstanding this suggested modification, the current TDAPA policy coupled with the lack of a sustainable permanent reimbursement pathway after the TDAPA period ends, not only stifles access to investment in new innovation, it also discourages manufacturers from studying ways existing drugs and biological products may support individuals living with kidney failure. We appreciates CMS seeking comments on how TDAPA could be improved. As KCP has raised on multiple occasions, the TDAPA period for new drugs or biological products in or outside of an existing functional category should be for at least three years. This policy would align the ESRD transition policy with that applied in the hospital outpatient department and ambulatory surgical center rules. Three years would provide at least 24 months of utilization and pricing information to allow for a more accurate inclusion of the new product into the bundled payment.

F. KCP continues to urge CMS to prioritize patient access to innovative treatment options by reforming the post-TDAPA Add-on Adjustment Methodology

KCP would like to take the opportunity in light of CMS raising the issue of post-TDAPA adjustments to reiterate our ongoing concerns that CMS policy has directly harmed patients by failing to provide a meaningful, sustainable pathway for truly new and innovative drugs and biological products to be reimbursement under the ESRD PPS. The three-year post TDAPA add-on payment adjustment falls far short of providing sufficient funding to support access to any new product. The example of Korsuva, as outlined in Section I, and the decision by GSK to stop providing its new treatment for anemia management because of the CMS reimbursement policy should spur a meaningful effort to develop a more balanced and patient-centered approach to funding innovation after the TDAPA period ends. We urge CMS to exercise its existing statutory authority and revise the post-TDAPA as follows:

- The adjustment should be made on a permanent basis and applied to claims when the product has been administered to a patient.
- The post-TDAPA amount should be determined by multiplying the most recent 12-month utilization for the product by the most recent full quarter of ASP (or WAC or manufacturer's invoice) divided by the total number of services when the product was administered.
    - The total amount should be set at 65% of the amount calculated above.
    - The amount should be updated annually by an inflationary index.
    - The amount should be applied immediately at the end of a product's TDAPA period.

The provision should not be implemented in a budget neutral manner. We urge CMS to include these recommendations as proposed policy changes in the CY 2027 proposed rule.

G. Additional Recommendations Related to the Drug Designation Process.

In addition to the recommendations noted above, we would like to offer two additional recommendations. Frist, we ask CMS to revise the drug designation process to make sure it is more transparent and inclusive. Second, we suggest CMS reconsider the use of functional categories to support innovation, foster competition as intended.

The current CMS process for determining whether a new drug or biological product is designated a renal dialysis service, or fits within a functional category or warrants a new one, lacks transparency and excludes meaningful stakeholder engagement. Yet, these determinations directly impact patient access and shape reimbursement pathways, such as TDAPA duration, post-TDAPA adjustments, and whether or not new funding is integrated into the bundle base rate.

At present, CMS conducts internal reviews of FDA materials and HCPCS applications without public input. Manufacturers and dialysis organizations learn of decisions through letter or policy transmittals. While outcomes may be referenced in the ESRD rule preamble, they are not subject to public comment or formal review. This closed process creates uncertainty for stakeholders, limiting their ability to anticipate or contribute to coverage and payment decisions. It also discourages investment in innovative therapies due to the unpredictability of reimbursement outcomes.

We recommend CMS adopt a more structured and transparent approach, modeled after the HCPCS code application process. This could include publishing preliminary determinations, hosting public meetings with opportunities for comment, and issuing final decisions online. Given the limited number of ESRD therapies currently in development, such a process would be relatively easy to administer, and would not impede timely decision-making, but instead foster greater stakeholder confidence and engagement.

In addition, KCP respectfully urges CMS to address what has become a serious barrier to patient access to medically necessary treatments: the reliance on functional categories as a proxy for defining innovation. This construct is not only misaligned with the federal government's own definitions of innovation—such as those outlined by the FDA and HHS, which emphasize clinical advancement and addressing unmet medical needs—but it also fails to foster the meaningful competition CMS has identified as a key policy goal.

By equating innovation with functional "newness", the policy creates a structural disincentive for the development of new therapies that may offer substantial clinical benefit but share superficial characteristics with older, less effective treatments. This misalignment has a chilling effect on innovation and represents a missed opportunity to improve patient outcomes. Moreover, the current reimbursement model actively undermines competition. Once the TDAPA period ends, there is no viable mechanism to support sustained access to new therapies. Providers are understandably reluctant to

prescribe treatments they cannot continue offering due to lack of reimbursement. This is not a theoretical concern—it is already playing out in the case of Korsuva.

Korsuva is the first and only FDA-approved therapy for CKD-associated pruritus (CKD-aP), a condition affecting approximately 35 percent[4] of ESRD patients. Despite its demonstrated clinical value, Korsuva was placed in a functional category alongside antihistamines like Benadryl—an agent approved in 1946 and widely regarded as ineffective for pruritus. As a result, no meaningful reimbursement mechanism exists to support Korsuva's continued use. Physicians reported withholding Korsuva prescriptions due to concerns about long-term sustainability, despite recognizing the drug's efficacy and the lack of viable alternatives. This policy failure has led to a stark mismatch between clinical need and utilization: fewer than 1 percent of eligible patients have received Korsuva, despite the condition's considerably higher prevalence.

CMS's proposed post-TDAPA add-on adjustment does not resolve the core issue. The methodology—distributing reimbursement across all dialysis treatments rather than those involving the drug—results in a payment of just $0.26 per treatment for a product with an ASP of approximately $50. This approach not only fails to support access to Korsuva, but actively disincentivizes providers from stocking or prescribing it.

We urge CMS to reconsider the use of functional categories as a gatekeeping mechanism for innovation and to adopt a reimbursement model that reflects clinical value, supports long-term access, and promotes competition. A patient-centered approach—such as the one proposed by the kidney care community—would ensure that reimbursement follows the patient and supports the continued use of effective, innovative therapies like Korsuva.

H. KCP remains concerned that TPNIES as currently designed does not support device innovation.

KCP recognizes that innovation in the area of dialysis treatments is lagging behind that for other chronic diseases. The primary difference between those conditions and kidney failure is that the Federal government is the primary insurer for the vast majority of individuals who require dialysis, while commercial insurers provide coverage for the vast majority of other chronic diseases. The Medicare rates for dialysis have chronically been underfunded. Therefore, while we were deeply disappointed that the preamble notes that CMS did not receive any TPNIES applications for CY 2026, we were sadly not surprised.

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[4] Sukul N, Karaboyas A, Csomor PA, Schaufler T, Wen W, Menzaghi F, Rayner HC, Hasegawa T, Al Salmi I, Al-Ghamdi SMG, Guebre-Egziabher F, Ureña-Torres PA, Pisoni RL. Self-reported Pruritus and Clinical, Dialysis-Related, and Patient-Reported Outcomes in Hemodialysis Patients. Kidney Med. 2020 Nov 21;3(1):42-53.e1. doi: 10.1016/j.xkme.2020.08.011. PMID: 33604539; PMCID: PMC7873756.)

KCP encourages CMS to recognize the flaws in the current policies and address them in CY 2027 rulemaking. Specifically, KCP recommends that CMS extend the TPNIES period to at least 3 years and provide an alternative pathway for TPNIES eligibility for devices designated by the FDA as Breakthrough Devices. We also request that CMS expand TPNIES to include capital-related assets. KCP would welcome the opportunity to discuss how these policies could be implemented this winter so that meaningful proposals could be included in the CY 2027 proposed rule.

III. KCP seeks to work with the Administration to improve the ESRD QIP.

KCP prioritized holding health care providers accountable for health outcomes in the early 2000s and worked to ensure that the Medicare ESRD program became first value-based program in Medicare in 2011. As the Trump Administration seeks to prioritize health outcomes over paperwork and administrative tasks, KCP would like to commit to partner once again with the Administration. Reform of the ESRD Quality Incentive Program (QIP) is long overdue. The Proposed Rule takes some important steps in that direction, but more can and should be done. Thus, in addition to responding to provisions outlined in the Proposed Rule and providing feedback on the Requests for Information (RFI), KCP includes suggestions about how to modernize the QIP so that it better supports transparency, empowers patient to control their health care, and creates meaningful provider accountability.

A. KCP supports the removal of measures related to social determinants of health

KCP supports the Administration's focus on improving health care in America by focusing on nutrition and environmental influences on health care. We know that these aspects of healthy living are critical to prevent and/or slow the progression of kidney disease. They are also important factors in better managing kidney disease even after it has progressed to kidney failure. We are committed to working with the administration on these aspects of health care for individuals living CKD and kidney failure.

However, we agree that the Facility Commitment to Health Equity measure and the two health-related social needs (HRSNs) screening measures are administratively intensive and should not be included in the QIP measure set. While it is important to identify barriers that affect the delivery of kidney care to individuals, the right balance must be struck to ensure that barriers to accessing health care are identified and addressed without inadvertently disincentivizing the provision of care to more medically complex patients. KCP previously expressed concern that these measures, particularly the Screen Positive metric, do not strike that balance, as this information is likely more indicative of the socioeconomic vulnerability of the patients a facility serves than of the quality of care it provides. Thus, we support removing these measures.

B. KCP supports adopting the modifications to the ICH CAHPS measure and reiterates the need to streamline its administration to reduce unnecessary burden on patients.

KCP believes it is critically important to measure patient experience related to their dialysis treatments and their interaction with nephrologists. We appreciate the ongoing efforts to address the burden of the ICH CAHPS measure on patients and supports the changes outlined in the Proposed Rule. In previous comment letters, KCP has supported the modification to the questions included in the instrument. We have also encouraged CMS to implement these changes within the ESRD QIP. As we have noted in previous comment letters, administering the current measure has created such a high level of patient burn-out with completing the lengthy survey twice a year that the measure is no longer valid. The Proposed Rules takes an important step toward addressing this problem by proposing modifications to the survey instrument.

However, a second critical step is necessary, which is to reduce the burden on patients that was created when CMS shifted to requiring survey administration twice a year. ICH CAHPS should be administered to patients once a year (not twice) to reduce burdens on patients while allowing information gleaned from survey responses to be acted on prior to the next survey administration. There are no data indicating that survey results would be less accurate if facilities were required to field it only once a year, while pre-pandemic data clearly demonstrate that the current twice-a-year fielding practice leads to substantial patient fatigue and non-compliance.

In addition, we reiterate our outstanding request that CMS adopt a CAHPS survey specifically designed to be administered to home patients and that CMS obtain endorsement of the new measure, which MedPAC and others in the community also have consistently requested. It is important that patients who select home dialysis modalities have the same opportunity to provide their input on their experience with the care they receive.

C. KCP seeks clarifications about the measure specifications.

KCP appreciates that CMS released the measure technical specifications with the publication of the Proposed Rule to allow the community and other stakeholders to identify and consider the impact of any changes from the previous specifications. While KCP has the resources to undertake this kind of analysis, we encourage CMS to highlight these differences and explain why the changes are being proposed in the future to increase transparency.

KCP identified several changes to the specifications, but fewer than in years past. While most seem innocuous, there are a few about which we would like to provide additional feedback and seek additional clarifications.

- KCP supports the refined definition of "facility claims" across several measures because it removes ambiguity present in the previous definition. We interpret the change to now include individuals with AKI who receive dialysis.

- As noted in earlier comments on the ICH CAHPS, administering the survey more than once a year is not a valid way to overcome the low response rate and, in fact, may be the reason so few patients respond when asked to do so. While reducing the number of questions will help reduce the burden on patients, this change alone is not enough to address the larger problem. We urge CMS to reduce the burden on patients by also fielding the survey only once a year.

- In the Kt/V PD measures, we believe the exclusion related to "fewer than 11 eligible patients" is a count of all patients in the facility, not just those with PD to allow more facilities to report this measure. We ask CMS to confirm this interpretation. We have a similar question regarding the Kt/V pediatric measures.

- Also with regard to the Kt/V measures, we support maintaining these separate metrics and would benefit from having more detail about how the overall score is calculated with these measures.

- For the PPPW clinical measures, we are concerned that the specifications exclude kidney-heart and kidney-liver transplants from the numerator. We request that CMS include these possible transplant combinations as well.

- Also in relation to the PPPW measure, we are concerned that the exclusions do not include active malignancies and ask for the criterion to be included.

- With the new references to "ESRD Administrative Data," it is not clear to KCP members what specific data will be used. We ask that before the final rule is published CMS update the technical specifications document to identify the specific data being used. It would also help if CMS would notify the community through its various ESRD list services when the change is made.

D. KCP urges CMS to modernize the ESRD QIP to more effectively hold providers accountable for quality outcomes by refining the ESRD QIP to eliminate measures focused on paperwork or that create administrative burdens without meaningful benefit to patients.

KCP sincerely appreciates the opportunity to provide recommendations to the Trump Administration about regulatory requirements that could be modified or streamlined to reduce administrative burdens without harming patients. In June 2025, KCP submitted comments through the HHS portal. We reiterate them in this comment letter on the QIP to urge the Administration to work with KCP so that these proposals could be part

of guidance and rulemaking in the coming months. The recommendations outlined below could be swiftly implemented and provide meaningful results aligned with your vision for CMS.

KCP encourages CMS to streamline the measures used in the ESRD QIP, in the Five Star/DFC program, and by the ESRD Networks. The chart below details the overlapping measure and inconsistencies in the specifications.

To streamline this effort, KCP recommends that CMS use only the following measures in the ESRD QIP.

- Standardized hospitalization rate measure (replacing the current ratio measure)
- Standardized readmissions rate measure (replacing the current ratio measure)
- Catheter > 90 Days Clinical Measure
- Bloodstream infection measure (updated to address the underlying validity issues)
- Patient Experience of Care: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Clinical Measure (modified to incorporate the experience of home dialysis patients as well)
- Hgb < 10 g/dL (replacing the standardized transfusion ratio measure)
- Serum phosphorous

As noted above, stars ratings would be awarded based on the QIP methodology and assigned based on the five tiers that are already delineated in the QIP program.

To ensure that DFC retains its quality assurance objective, KCP recommends that it contain the following measures to provide transparency:

- Adult Hemodialysis Kt/V Adequacy Measure
- Adult Peritoneal Dialysis Kt/V Adequacy Measure
- Pediatric Hemodialysis Kt/V Adequacy Measure
- Pediatric Peritoneal Dialysis Kt/V Adequacy Measure
- Percentage of patient months of pediatric in-center hemodialysis patients with documented monthly nPCR measurements
- Clinical Depression Screening and Follow-Up Measure
- Medication Reconciliation Reporting Measure

Given that we anticipate CMS proposes to eliminate the social determinant of health-related measures in the upcoming proposed rulemaking, as it has done for the Part A providers, we have not included them in either program. We also urge CMS to eliminate the hypercalcemia measure, which the kidney care community has noted for several years is meaningless and not relevant to patient care. We also urge CMS to eliminate the transplant waitlist measures, which more accurately measure transplant centers than dialysis facilities that have little influence over hospital waitlist criteria or whether a patient is listed for

transplant. KCP has developed a transplant measure set that it would welcome the opportunity to work with CMS to test and ultimately have incorporated into one of the quality programs.

Within the DFC program, we request that CMS eliminate the following measures:

- Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities
- Standardized Ratio of Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) for Dialysis Facilities
- Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

We remain concerned that these measures have validity and reliability problems.

Summary of Inconsistencies in ESRD Quality Programs

Measure	Differences
BSI	Positive blood cultures (PBCs) are considered BSIs in NHSN and only the SIR (observed PBCs / predicted PBCs) is used by CMS for QIP and Five Star. The Network uses variable definitions.
ICH CAHPS	Star ratings updated twice per year, while QIP follows a calendar-year (CY) survey. Different timeframes can lead to incongruent results where clinic can perform well in one program but poorly in another.
Hospitalizations	The SHR measure is the same for both QIP and Five Star; however, there are a few differences related to assessing performance. QIP Only: For facility exclusions, calculations will exclude the months covered by a granted ECE (see Section 3.4). - See 2.13.7 of the CMS ESRD Measures Manual (https://www.cms.gov/files/document/esrd-measures-manual-v101.pdf). Five-Star Only: 2.13.16 Flagging Rules for Dialysis Facility Measures. Per CMS Measures manual: "As currently implemented for Dialysis Facility Measures, for reporting purposes we identify outlier facilities from amongst those with at least five patient-years at risk during the time period. If the 95% interval lies entirely above the value of 1.00 (i.e., both endpoints exceed 1.00), the facility is said to have outcomes that are 'worse than expected'. On the other hand, if the 95% interval lies entirely below the value 1.00, the facility is said to be better than expected. If the interval contains the value 1.00, the facility is said to have outcomes that are 'as expected'."

Measure	Differences
	There are no specifications when hospitalization is part of a Network program.
Readmissions	SRR has two separate measures for QIP and Five-Star. Slight differences in the measure specifications (detailed below) lead to differences in SRR for QIP and Five-Star. For example, SRR for Five-Star was 26.4 and 25.87 in QIP (expressed as rates). While the measure name, description, rationale, and type are similar - Five-Star uses "ratio" only whereas QIP states "A lower rate/ratio indicates better quality." in Sections 2.10.5 and 2.11.5. Additionally, QIP includes a statement in the Facility exclusions that states: "Calculations of index discharges will exclude the months covered by a granted ECE (see Section 3.4)." The numerator and denominator statements are the same. However, the Index Discharge Exclusions vary. QIP also has a patient exclusion section that is not included in the Five-Star measure: "Patient with a functioning transplant on the date of the index discharge. Patient is determined to have a functioning transplant on the discharge date when the discharge date occurs on or between the transplant start and end dates." Mapping to facilities is essentially the same with one addition in QIP: "ESRD QIP assigns to the CCN the facility used as of date of discharge." Defining Readmissions section has several variances as well, specifically related to classification of planned/unplanned admission (QIP refers you to Section 2.11.17, Five-Star continues the conversation in that same section). Note: Both QIP & Five-Star use the same algorithm for determining planned admissions: Yale New Haven Health Services Corporation/Center for Outcomes Research & Evaluation (YNHHSC/CORE). However, they are similar in the 4-30 day timeframe for unplanned readmissions. QIP also includes a definition of the calculation of the National Average whereas Five-Star does not. Finally, the risk adjustment approach used in the model for the SRR was adapted from CMS' Standardized Hospitalization Ratio (SHR)

Measure	Differences
	and CMS' Hospital-Wide Readmission (HWR) measure is the same for both QIP & Five-Star.
	There are no specifications when hospitalization is part of a Network program.
Mortality	Five Star removes patient deaths which occur 30 days after the patient was last dialyzed in a facility. Claims-based measures continue to count those deaths.
PPPW/Waitlist	The PPPW measure is the same for both QIP and Five Star; however, there are a few differences related to assessing performance: QIP only: For facility exclusions & denominator statement, calculations will exclude the months covered by a granted ECE (see Section 3.4). - See 2.16.7 of the CMS ESRD Measures Manual. Five-Star only: 2.16.14 Creating Interval Estimates "The 95% confidence interval gives a range of plausible values for the true waitlist percentage. The upper and lower limits of the confidence interval enclose the true percentage approximately 95% of the time if this procedure were to be repeated on multiple samples. A two-sided Wald test (0.05 significance level) is used to measure the statistical significance of (or evidence against) the hypothesis that the PPPW for a facility is the same as (neither higher nor lower than) that from the national average percentage waitlisted. A p-value of less than 0.05 is usually taken as evidence that the facility PPPW differs from the national PPPW." Five-Star only: 2.16.15 Flagging Rules for Dialysis Facility Compare "Facilities were classified as "Better than expected", "As expected", or "Worse than expected" based on their Z score of the logit of PPPW. The z score value is much more likely to follow a normal distribution than PPPW itself, due to the symmetry and lack of range restrictions of the transformed version" Additionally, Five-Star has an additional waitlist measure that is not included in QIP: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR) Measure.

Measure	Differences
Long-term Catheter	The LTCR measure is the same for both QIP and Five; however, there are differences related to assessing performance. QIP Only: For denominator exclusions, for new facilities only, the month in which the CMS Certification Number (CCN) becomes effective and the following three months (see Section 3.5). - See 2.1.9 of the CMS ESRD Measures Manual 3.5 Start Dates for Reporting Measures Data by New Facilities New facilities are required to collect and report EQRS or NHSN data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is four months after the month in which the CCN becomes effective. For example, if a facility is certified in January of the performance period, the facility is not required to report data until May 1 of the performance period. Note: Five-Star continues to include a standardized fistula rate measure whereas QIP removed it to align with current dialysis guidelines.
Hypercalcemia	Hypercalcemia is a different measure for QIP (reporting) and Five-Star (Clinical performance). Five-Star only: Type: Intermediate Outcome - Calculation: Proportion of all adult patient-months (Medicare and non-Medicare patients) with three-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL or missing (CBE ID 1454). QIP Only: Type: Process - Calculation: Percentage of all adult patient-months where total uncorrected serum or plasma calcium lab values were reported in EQRS during the performance period. Facility exclusions include: ECEs, CCN certification date on or after 9/1 of performance period, and for new facilities only, the month in which the CCN becomes effective and the following 3 months. Pediatric patients are identified differently (See 2.8.10 for details). Patients are also mapped to facilities differently.
Flu Vaccine	Both use NHSN guidelines and logic as data sources, but for networks, it all depends on the individual network as to what metric they are looking at; the National Forum of ESRD Networks provides a vaccination toolkit with a data collection tool as well.

Measure	Differences
Pneumonia	Both use NHSN guidelines and logic as data sources, but for networks it depends on the individual network as to what metric exactly they are looking at; the National Forum of ESRD Networks provides a vaccination toolkit with a data collection tool as well.

In addition to the quality programs noted above, the CDC NHSN program requirements create a series of burdensome barriers that make reporting incredibly challenging. This problem spans all CDC NHSN reporting requirements for dialysis facilities. We encourage HHS to partner with and engage directly with the dialysis providers to obtain a complete picture of what needs to be done. Additionally, HHS and CDC should consider rebaselining for the purposes of SIR on a predictable schedule and review current language for specificity on definitions. HHS should consider working with CDC on an analysis for the best measure for dialysis outcomes as it relates to bloodstream infections (e.g., a BSI rate as opposed to the SIR). Finally, we recommend CDC provide more timely published industry data. For purposes of the RFI, we are highlighting the following challenges and specific recommendations to address them in relation to the submission of data for the Bloodstream Infection measure.

We also want to highlight that CMS should try to avoid making changes to measures before the end of the performance year because it can create an unfavorable and concerning precedent.

E. KCP supports the structural proposals related to the performance standards, eligibility requirements, and payment reduction scale.

Once again, KCP applauds CMS for recognizing the importance of maintaining a consistent methodology when it comes to the structural components of the ESRD QIP, which include establishing performance standards, eligibly requirements, and the payment reduction scale. The Congress established the ESRD QIP to hold providers accountable for the quality of care provided to individuals living with kidney failure, create transparency with regard to facility performance, and empower patients to make their own health care decisions. Maintaining consistency in the methodology allows for year-over-year comparisons and supports transparency by ensuring methodology changes do not mask underlying quality performance.

We do note, however, that the minimum Total Performance Score (mTPS) jumps from 51 to 56 for PY 2028. Historically, the mTPS has not jumped 5 points in a single year, even though it has moved up and down over time. This proposed change would result in about 20 percent more facilities receiving some level of penalty than in the previous year. This result seems rather dramatic given that historically any year-over-year increase in penalties has been significantly less. We recognize that using the CY 2024 data may result in a change between the proposed and final rule, but it is important to understand why this

change is happening given so few changes in measures and methodology between the payment years. As we understand the proposed rule, the methodology for calculating the mTPS has not changed, but it is less clear how that methodology resulted in such a significant shift in the points. We ask CMS to provide the details why the mTPS change is so dramatic.

IV. KCP appreciates the opportunity to provide comments on current state of health information technology us in dialysis facilities and future measure concepts.

A. Based on a survey of KCP members, the current state of health information technology (IT) use in dialysis facilities is limited in light of the financial barriers created by chronic underfunding of the Medicare ESRD PPS and the lack of any Federal dollars to support the adoption of health IT.

1. Overview of Responses to KCP Member Survey: Several Challenges Exist with Regard to EHRs and Health IT that Could Be Addressed with Support from CMS.

KCP appreciates the opportunity to provide insights into the status of health IT use in dialysis facilities. We also understand that CMS is eager to shift toward more eClinical Quality Measures (eCQMs) that rely upon strong health IT systems and interoperability. To support CMS with this request for information, KCP conducted a survey of our members (dialysis facility and nephrologists) based on the questions presented in the Proposed Rule. We provide the responses to each question in the following sections of this letter; however, we also want to share an overview of the themes from members' responses.

To level set the discussion, it is important to recall that while the Federal government provided financial and technical support for other health care providers to adopt electronic health records (EHRs) and robust health IT systems, dialysis facilities and many nephrologists were excluded from these programs. Because Medicare is the primary payer for more than three-quarters of all dialysis patients, Medicare rates determine whether facilities and nephrologists have sufficient resources to adopt not only treatment innovations but also practice innovations, such as health IT systems. MedPAC continues to report zero and negative Medicare margins for dialysis facilities. These margins demonstrate that there is often not enough cash to provide the necessary health care services, less alone cover the cost of expensive EHRs or health IT systems. As a result, it is no surprise that there is significant variability with regard to the use of EHRs and health IT systems among dialysis facilities and nephrologists. Given this current patchwork system, KCP urges CMS to adopt provide funding as was given to other providers to allow them to transition into EHRs and health IT systems.

The KCP survey demonstrated that dialysis facilities and nephrologists support the use of EHRs and health IT systems to maintain patient records. Despite that, many current CMS programs are burdensome and complex, requiring the collection of an ever-changing list of data elements. These elements are not always standardized. Some, such as those required by the ESRD Networks, still require manual data entry.

Despite this strong support for leveraging technology to streamline current reporting requirements and improve patient care, there is significant variability among providers with regard to the adoption and implementation of EHRs and health IT systems. Interoperability, especially with hospitals, remains problematic for many providers.

Another barrier to achieving interoperability is also lack of standardization. In particular, CMS programs lack basic standardization. The current state of the various ESRD quality programs and the lack of standardization of the measure specifications shows that significant work will need to be done despite the progress already made. Thus, along with financial support to adopt EHRs and health IT systems, CMS should draw on its authority under HIPAA to ensure standardization, especially in its own programs, to support true interoperability.

The survey also shows that FHIR is not widely used in this community, especially for transmitting quality data. That may be due to the fact that as CMS was developing its work on FHIR, it had tasked dialysis facilities with adopting an entirely different system to support EQRS. The community and CMS have accordingly spent a great deal of time and effort to be compliant with that system. As noted already, to make this shift to FHIR will take time, financial resources that facilities and nephrologists currently do not have, and technical assistance.

Another challenge to interoperability within kidney care is the challenges and barriers with hospitals and hospital systems to share health care information with dialysis facilities and nephrologists. Interoperability, which includes making sure these systems include all of the ESRD data elements) could help solve this problem, but for that to work, hospitals and the EHR vendors would have to be willing to ensure that their systems have the ESRD-specific data and communicate with those belonging to facilities and nephrologists. Based on our past experience, achieving such interoperability may require CMS to establish interoperability and data sharing requirements for these providers as well.

KCP agrees that the adoption of health IT and EHRs supports interoperability that could transform the treatment of kidney disease and kidney failure to support improved patient outcomes, better disease management, greater transparency, and more provider accountability. As a result, Medicare spending for hospitalizations and other costs outside of the dialysis facility and nephrologists' offices that result from complications dialysis patients could be reduced.

In sum to address current gaps, promote interoperability, and support FHIR standards, KCP asks CMS to: (1) establish a program for dialysis facilities and nephrologist to provide financial and technical assistance to these providers to adopt or adapt existing EHRs and health IT systems; (2) provide this support for at least 3-5 years; and (3) work to incorporate standardized renal specific data element and other aspects of health IT systems to support interoperability within CMS programs and with commercial insurers, including Medicare Advantage insurers.

2. Response to Specific RFI Questions

KCP fielded the CMS questions in a survey format to dialysis organizations and nephrologists who are members of KCP. We received responses from nearly all of our dialysis organization members, including organizations that are not individually members of KCP but part of the Kidney Care Council or Renal Healthcare Association. We also received responses from a few nephrologists/nephrology practices. While not necessarily a representative sample of the industry, we believe the survey results can provide important information about the status of EHRs and health IT systems, as well as the potential for integrating eCQMs into the QIP program.

- **What health IT does your facility use to maintain patient records, and are these health IT certified by the Assistant Secretary for Technology Policy (ASTP) and the Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP)? If your facility uses EHRs that are not certified by ONC, please specify. Does your facility maintain any patient records outside of these electronic systems? If so, is the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems?**

The vast majority of respondents (nearly 70 percent) rely upon their own company-specific EHR or another EHR that is not one of the major national EHRs, such as EPIC. A few facilities rely solely on the EQRS system. Most are not certified by ASTP and ONC. About half of the respondents also maintain patient records outside of these electronic systems to support manual submissions required by CMS for quality reporting. Of these additional records, only about 44 percent of respondents reported that their records are organization in a structured format using codes and recognized standards that would allow for data to be exchanged electronically with other systems.

- **Does your facility submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your facility currently exchange health information with other healthcare providers or systems, specifically between facilities and other provider types? What are the challenges?**

More than 80 percent of facilities responding submit patient assessment, which we assume means through non-FHIR-based EQRS, data to CMS through their current IT system. A little fewer than half submit it directly, with the remainder submit data through a qualified registry or health information exchange. No one reported relying upon a third party intermediary service. More than 60 percent of the data exchanges occur between facilities and nephrologists, with about one-third between facilities and hospitals. No organization reported being able to share data electronically directly with outpatient hospitals, primary care physicians, other types of physicians, SNFs/nursing homes, or mental/behavioral health facilities; however some facilities report sharing data using HEIs.

- **Are there any challenges with your current electronic devices that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit assessment data to CMS? Please specify.**

Nearly 70 percent of respondents reported challenges with their current electronic devices that hinder their ability to achieve interoperability. The most common reasons were lack of standardization and the lack of interoperability generally. Other barriers included limited internet access or lack of internet connectivity; other provider(s) not using a health IT system or EHRs; and lack of certification.

- **What challenges or barriers does your facility encounter when submitting quality data to CMS as part of the ESRD QIP? What opportunities or factors could improve your facility's successful data submission to CMS?**

All respondents reported encountering challenges when submitting data to CMS as part of the ESRD QIP through EQRS. The number one issue was problems with the CMS interface. Facilities also reported problems with system integration and standardization. Other barriers include: API challenges, data silos, incomplete or inaccurate data, infrastructure upgrade requirements, and the lack of regulatory clarity as to what must be reported.

Fifty-percent of responds indicated that standardization of data elements, definitions, and similar items would improve their facility's ability to successful submit data to CMS. One-quarter noted that streamlining employee credentials and the sign-on process would help. Other opportunities for improvement include improving APIs and clarifying regulatory guidance.

- **What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR-based technology in your facility for the submission of the data to CMS?**

How could these resources be designed to minimize complexity and burden on healthcare providers while ensuring the protection of patient care and maintaining staffing capacities during implementation? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?

Nearly 90 percent of respondents said they could implement a FHIR-based technology, but were quick to point out that they do not currently have the resources – financial or technical – to do so today. If such funds and assistance were provided, 50 percent indicated that it would take them 12-24 months to do so. Nearly one-quarter indicated it would take more than 24 months. Eighty percent of respondents estimated that it would take between $1 million and $1.5 million to adopt FHIR-based technology. More than 60 percent said that standardized data elements and specifications reflecting the nuances and realities of renal specific data elements (such as dry weight, lab values, vascular access, etc.) would be needed for the successful implementation of FHIR-based technology. More than one-quarter added that the recognition of resources necessary to implement new IT through dedicated Medicare reimbursement would be needed. Others added that instruction modules for employees would be helpful.

In terms of the design of such resources, responded requested: clear requirements for providers with input from stakeholders; realistic timeframes for standards implementation; the assurance that data collected are relevant to improving patient care/outcomes; the reduction of manual data collection and automating data collection; and the provision of bonus incentives for adoption prior to final deadlines.

They noted that QIOs could help enhance such support primarily by decreasing data entry time for dialysis staff and decreasing the burden on dialysis facility clinical staff on manually accessing outside clinical records. A few suggested these and other similar entities would not be helpful at all.

- **How do you anticipate the adoption of FHIR-based standards for reporting patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?**

While 30 percent of respondents said that the adoption of FHIR-based standards would have minimal impact on quality of care, nearly 40 percent thought it would improve communications between nephrologists and dialysis facilities, while more than 15 percent said it could improve post-hospitalization discharge transitions of care. Others thought it might improve the tracking of hospitalizations and improve the reconciliation of clinical data elements and medications from inpatient to outpatient settings.

- **Does your facility have any experience using technology that conforms to a version or versions of the United States Core Data for Interoperability (USCDI) standard for data? Is your facility using technology that utilizes APIs based on the FHIR® standard for electronic data exchange? If so, with**

whom are you exchanging data using the FHIR® standard and for what purpose(s)? Has your facility used a SMART on FHIR®19 application? If so, was the SMART on FHIR® application integrated with your EHR? Additionally, what benefits or challenges have you experienced with the implementation of FHIR® using APIs or USCDI?

While 45 percent of respondents indicated that they have experience using USCDI, 55 percent do not. Nearly 80 percent of facilities do not use technology that relies on APIs based on the FHIR standard for electronic data exchange. Only one respondent indicated that it could use this standard to exchange data with inpatient hospitals. Even this one respondent was not using it to exchange data with any other type of provider. Similarly, only one respondent has used SMART on the FHIR®19 application, which appears to be integrated into the respondent's EHR. One key challenge is the continued presence of closed or fragmented EHR ecosystems that limit third-party access to patient data. Despite FHIR-based API requirements, many certified EHRs still control access through proprietary gateways or business agreements, undermining the promise of open innovation.

- **What might encourage your facility and/or vendors to participate in testing to explore options for transmission of assessments, for example testing the transmission of a FHIR-based assessment to CMS?**

Respondents agreed that bonus payments and standardization were the two most important ways CMS could encourage providers to participate in testing options for transmission assessment.

- **How could the Trusted Exchange Framework and Common Agreement™ (TEFCA™) support CMS quality programs' adoption of FHIR-based assessment submissions consistent with the FHIR® Roadmap (available here *https://rce.sequoiaproject.org/three-year-fhir-roadmap- for-tefca/)*? How might patient assessment data hold secondary uses for treatment or other TEFCA exchange purposes?**

More than 40 percent of respondents indicated that CMS should provide clear and standardized guidance related to the dialysis-specific data elements. Twenty-five percent said provided a similar response: CMS should make sure that IT standards capture the nuances and complexities of dialysis. Others suggested that CMS quality reporting requirements should align with any TEFCA-advanced standards to ensure interoperability. Realizing the potential for TEFCA will require CMS and ONC to ensure TEFCA is actually inclusive of specialized providers like dialysis organizations.

B. KCP remains concerned that adding more measures to the ESRD QIP will dilute the impact and accountability with regard to the measures patients identify as most critical to their care.

As noted in our response to the broader HHS RFI, KCP remains committed to improving the ESRD QIP program so that it fulfills Congressional intent and meets the Administrator's vision for CMS to improve patient outcomes, create greater transparency, and hold providers accountable for the quality of care they provide to patients. During the last several years, CMS has added more and more measures to the QIP without retiring a similar number. Many of these measures lack actionability by dialysis providers or even nephrologists, which means these providers cannot take specific actions to improve what is being measured. Some lack validity or reliability, meaning the metric and its results are not accurate. To that end and for the detailed reasons in the follow sections, we urge CMS not to add more measures to the ESRD QIP until KCP and the Administration can have more constructive conversations to assess and modernize the program. To avoid unnecessary delay, we encourage CMS to begin engaging with us as soon as possible.

1. Given that the primary purposes of the ESRD QIP is to enhance the quality of care delivered to patients and to increase transparency and accountability, the ESRD QIP is not the appropriate place to include a measure of interoperability. Instead, CMS should provide financial and technical resources to support interoperability.

As our response to the first RFI about health IT demonstrates, KCP agrees that more needs to be done to encourage improved interoperability in this area of health care. While other Medicare providers have had access to Federal funding and technical support for health IT adoption, dialysis facilities have been forgotten. KCP supports efforts to address this gap and efforts to promote interoperability. For example, KCP has been asking the Federal government for more than 15 years to require inpatient hospitals to respond to legitimate requests for information about dialysis patients when they are discharged from the hospital. Given that the average dialysis patient is hospitalized approximately 2 times each year,[5] facilities need the information to ensure the seamless transition of care after a patient has been hospitalized. Yet, many hospitals simply do not respond, while others refuse to provide the information.

In order to meet the definition of interoperability outlined in the Public Health Service Act, dialysis facilities need the same financial support that other providers received. For example, in our survey of dialysis facilities and organizations nearly all indicated a strong desire to improve interoperability while noting that the lack of resources was the primary barrier stopping them from pursuing that goal. Historically CMS provided individual hospitals with $2 millions or more to adopt EHRs. Similar funding for dialysis

[5]USRDS. *Annual Data Report*. ESRD: Ch. 5 (2024).

facilities is necessary to support the adoption of EHRs and other health IT systems necessary to promote interoperability.

While KCP supports interoperability efforts, we do not think a measure of interoperability in the ESRD QIP is a good fit. As noted, the purpose of the QIP is not to measure or incentivize the adoption of health IT, but rather to focus providers on improving patient outcomes, providing transparency for patients and care-partners as to facility performance, and holding providers accountable for their performance. An interoperability measure simply does not fit within the statutory scope of this program. Thus, we ask CMS instead to provide financial and other assistance that will incentivize the adoption of the health IT necessary to support greater interoperability.

2. **While KCP supports efforts to incorporate measures of patient satisfaction, there is no appropriate metric(s) to support adding a measure of "well-being" to the QIP in near future.**

KCP agrees that well-being is important for all Americans, including individuals living with kidney failure. While there are psychological assessment tools of well-being that mental health professionals use to assess and work with patients, improving a patient's happiness and satisfaction with life is outside the scope of practice and clinical expertise of nephrologists and dialysis facilities. 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 they can directly impact. Patients and patient advocates who work with KCP repeatedly have urged CMS not to adopt measures that are outside of this scope and that are aspirational in nature, such as those trying to measure happiness or satisfaction with life. They maintain that the QIP needs to be focused on whether or not dialysis facilities are providing the renal dialysis services. These patients work with other providers to address mental health or other services that are outside of the facility's narrow scope. Moreover, there is no metric that could be adopted to measure well-being. There is also no clinical literature describing how dialysis facilities can improve a patient's happiness or satisfaction with life that would support the development of such a measure in the near term. We urge CMS not to pursue adding a measure of well-being to the QIP.

3. **KCP agrees that nutrition is a critical aspect of caring for individuals with kidney disease and recommends that CMS consider opportunities to develop an appropriate measure for earlier stages of CKD where it could be more impactful and support the delayed onset of kidney failure.**

As part of KCP's "Strategic Blueprint for Advancing Kidney Care Quality," KCP suggested that Nutrition Management be included in internal quality improvement (IQI) activities, such as deploying standardized protocols, identifying and disseminating best practices, and benchmarking. It found that these activities are highly effective drivers of

improving care. Protein-energy wasting (malnutrition) occurs frequently in patients with renal failure and is associated with increased morbidity and mortality. Nutrition-related concerns include maintaining acceptable weight and serum proteins (e.g., albumin), minimizing renal bone mineral disease, and reducing cardiovascular risk. IQI activities focusing on iterative nutritional status assessments, counseling and, when indicated, supplementation, can improve outcomes and quality of life. However, current metrics, such as those related to albumin, are not appropriate because of the challenges of assessing the based on different modalities of dialysis and the interaction of other conditions that can confound the results. Our experts agree that an albumin measure by itself is not an appropriate metric for nutrition.

KCP supports the Administrator's vision to focus on the agency on preventative care as one way to stop chronic disease. As such, we believe that a nutrition measure would be more appropriate as a CKD measure in the pre-dialysis space. Thus, we encourage CMS to work with KCP and particularly the Renal Physicians Association and the American Society of Nephrology to consider a measure for the physician quality programs.

4. **There is current insufficient literature addressing the role of physical activity in patient outcomes related to dialysis services to support a measure of physical activity.**

KCP members, especially the clinicians, are unified in their view that while there is some general literature about the need for physician activity, there is currently no clinical literature to support the development of a measure of physical activity specific to individuals receiving dialysis. There is no consensus about what type of physical activity should be measured, how long the activity should last, or how to quantify the effort exerted during the activity. While we realize that there are measures in the SNF VBP related to physical activity, patients in SNFs are residents. As such, they are with their providers 24-7 which is not true of patients receiving services from a dialysis facility. The MDS also includes significantly more data than the current information systems and data available to dialysis facilities upon which they could take action. Given the current lack of clinical literature in this area, KCP would not support a measure of physical activity being added to the QIP.

5. **More research and work needs to be undertaken before the community can recommend specific measures related to CKD early detection, treatment, and the delay of the progression of ESRD in all treatment settings.**

KCP supports the effort address chronic diseases before patients develop them by tackling the root causes that lead to their development. Many of our members actively engage in efforts to promote early detection, provide preventative care, and better manage early stages of CKD in an effort to delay, and in some cases, prevent the onset of kidney failure. As currently structured, the Medicare ESRD program does not cover chronic kidney

disease prior to a patient having been diagnosed with kidney failure for at least three months. So, while the ESRD QIP may not be a place where such measures could be included, we support future efforts to develop valid, reliable, and actionable outcome-based measures for CKD.

According to the Battelle Partnership for Quality Measurement website, there are currently nine CKD measures. While some have previously been in physician quality programs, these were removed because they are process-based measures. Given the lack of meaningful measures in this area and the need to address barriers to accessing early detection and treatment (which includes commercial plans being incentivized not to provide preventative CKD services), we encourage CMS to work with KCP to develop a comprehensive approach that embraces policy changes beyond the adoption of measures to support the Administration's efforts to address the growing burden of CKD.

V. KCP Continues to Support the AKI Payment

KCP continues to support the AKI payment amount and ability for AKI patients to receive home dialysis. We believe clinically appropriate innovative drugs and devices should be accessible to AKI patients, especially given recent policy changes allowing AKI patients to dialyze at home. We appreciate being able to work with the Agency to ensure access for these patients.

VI. KCP Supports Sunsetting the ETC Model

While the goals of the ETC Model were laudable, KCP supports early termination of the model. As we have noted previously, a penalty-based approach in a chronically underfunded system will not result in improved patient outcomes. It will not meet the goals of this Administration to use evidence-based innovation to improve patient outcomes, better manage chronic disease, and reduce overall Medicare spending.

We encourage CMS to work with KCP as we develop comprehensive system reform to modernize the ESRD payment system and address flaws in the current PPS and QIP programs. USRDS reports that nearly one-quarter of Medicare expenditures for beneficiaries with kidney failure are for inpatient hospital services. Reforming the payment system to address the chronic underfunding of the ESRD PPS, supporting a sustainable pathway for innovation to protect patient access to such innovation, and making the quality programs more meaningful and less burdensome will lead to improve patient outcomes and reduce spending in other parts of Medicare.

VII. Conclusion

Thank you again for providing KCP with the opportunity to provide comments on the proposed rule. Please do not hesitate to reach out to our counsel in Washington, Kathy Lester, 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,

Mahesh Krishnan MD MPH MBA FASN
Chairman
Kidney Care Partners

Appendix: KCP Members

Akebia Therapeutics, Inc.
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Atlantic Dialysis Management Services, LLC
CorMedix, Inc.
CSL Vifor
DaVita, Inc.
Diality, Inc.
Dialysis Care Center
Dialysis Patient Citizens, Inc.
Fresenius Medical Care North America
Greenfield Health Systems, Inc.
Kidney Care Council
North American Transplant Coordinators Organization
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.
Vantive