August 29, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

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-1830-P)

Dear Administrator Oz:

As CMS finalizes policies for the CY 2026 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), we urge the agency to take decisive steps to safeguard access to life-sustaining dialysis care for Medicare beneficiaries. Members of the Renal Healthcare Association (RHA) remain deeply committed to providing high-quality treatment to those we serve. However, escalating supply costs and persistent workforce shortages paired with inadequate reimbursement are placing increasing strain on dialysis facilities, especially small and independent providers that care for some of the most medically complex and vulnerable individuals in the Medicare program.

RHA is a voluntary organization representing dialysis providers throughout the United States that provide life-sustaining dialysis services to nearly 135,000 Medicare beneficiaries. Our membership primarily includes small and independent for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in free-standing, hospital, and skilled nursing facility (SNF) based facilities. We strongly support efforts by CMS to improve health outcomes, lower costs, enhance care quality, and reduce disparities for Medicare beneficiaries with ESRD.

The recommendations outlined in this letter reflect urgent steps CMS must take to address the ongoing reimbursement challenges facing dialysis providers. Looking to the future, however, RHA is eager to collaborate with the agency on longer-term, structural improvements to the ESRD PPS to ensure a more sustainable and responsive payment system for the future. CMS implemented the ESRD PPS on January 1, 2011, replacing the previous basic case-mix adjusted composite payment system and the methodologies for the reimbursement of separately billable outpatient ESRD services.[1] As we articulate throughout this comment letter, the ESRD PPS has struggled to keep pace with the evolving landscape of ESRD treatment, creating challenges in fully meeting its intended goals. Over the past 14 years, advancements in medical technology, evolving treatment protocols, and a growing understanding of the comprehensive needs of ESRD patients have exposed limitations within the current PPS model, making it less suited to the diverse and complex nature of ESRD care.

The RHA appreciates CMS' proposals to help refine the ESRD PPS to better serve dialysis patients in CY 2026. However, we encourage CMS to explore new reimbursement methodologies that are better suited

[1] CY 2011 ESRD PPS Final Rule

for small and independent dialysis providers, moving beyond the current limitations of the PPS bundled payment system. While RHA is encouraged that Medicare fee-for-service (FFS) payment growth briefly outpaced cost growth between 2022 and 2023, per the March 2025 Medicare Payment Advisory Commission (MedPAC) report[2], this modest improvement does not offset years of chronic underpayment. MedPAC has consistently reported since 2019 that the cost per dialysis treatment has increased faster than FFS payment rates.[3,4,5] RHA remains concerned that cost growth will once again surpass payment increases, particularly as labor, supply, and capital expenses continue to rise. Despite payment briefly outpacing cost growth, MedPAC reported that the Medicare margin for FFS dialysis providers remained negative in 2023, at -0.2 percent, highlighting the ongoing need for continued payment increases to support sustainable dialysis care.[6]

A more comprehensive and adaptive payment system is necessary to ensure that all ESRD patients receive holistic care that goes beyond dialysis treatments to include support for their overall well-being. And, by adopting a more flexible and adaptive payment model for ESRD care, CMS can better support the development and integration of innovative treatments and technologies that can improve ESRD patient outcomes and experiences. We look forward to working collaboratively with the agency to improve the ESRD payment system to ensure that all Medicare beneficiaries with ESRD have access to the high-quality care they deserve.

RHA offers its comments on "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-1830-P).[7] We believe our recommendations will help to improve access to high-quality care for vulnerable dialysis beneficiaries and ameliorate the impact of ongoing staffing and supply shortages on the dialysis provider community.

Below, we summarize our recommendations in response to the proposed rule:

CY 2026 ESRD PPS

1. **ESRD PPS Base Rate:** RHA urgently requests that CMS provide a one-time, non-budget neutral adjustment to increase the ESRD PPS base rate. A net increase of 2.7 percent over the CY 2025 base rate, as proposed, is not sufficient to cover the costs of furnishing care to a Medicare beneficiary with ESRD.
2. **ESRD Market Basket:** RHA requests that CMS establish an ESRD market basket forecast error adjustment policy to ensure that inaccuracies in market basket projections do not result in undue financial strain on dialysis providers.

[2] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch5_MedPAC_Report_To_Congress_SEC.pdf
[3] https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch6_v2_SEC.pdf
[4] https://www.medpac.gov/wp-content/uploads/2023/03/Ch6_Mar23_MedPAC_Report_To_Congress_SEC.pdf
[5] https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch5_MedPAC_Report_To_Congress_SEC.pdf
[6] *Ibid.*
[7] CY 2026 ESRD PPS Proposed Rule

3. **ESRD Wage Indices:** CMS should revisit the current ESRD wage index methodology to evaluate how accurately it reflects the true labor costs of providing dialysis care, particularly the training, staffing, and care coordination demands required under the Conditions for Coverage.

4. **Outlier Policy:** CMS should update the Medicare Allowable Payment (MAP) and fixed dollar loss (FDL) amounts for both adult and pediatric patients in a manner that meaningfully expands the number of patient months qualifying for outlier payments, ensuring the policy better targets the 1.0 percent goal.

5. **Changes to the Transitional Drug Add-on Payment Adjustment (TDAPA) eligibility policy:** CMS should finalize its proposal to apply a three-year eligibility window from the date of FDA approval for TDAPA applications submitted on or after January 1, 2028. This change aligns with the existing Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) timeframe and provides manufacturers with ample time to prepare for market entry while promoting consistency across transitional payment policies.

6. **Proposed Payment Adjustment for ESRD Facilities in Certain Non-Contiguous States and Territories:** CMS should finalize the proposed Non-Contiguous Area Payment Adjustment (NAPA) for CY 2026 but implement it as a non-budget neutral adjustment to fully account for the elevated non-labor costs faced by ESRD facilities in these regions. Additionally, CMS should closely monitor supplier pricing and cost trends across all geographies to guard against cost inflation and ensure payment adjustments reflect genuine cost differentials.

Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

7. **AKI Dialysis Payment Rate**: RHA requests CMS revisit the AKI payment rate methodology to ensure it fully reflects the higher costs of providing dialysis to patients with AKI , particularly given the increased frequency of monitoring, individualized care, and clinical oversight necessary to support kidney function recovery across settings.

ESRD Quality Incentive Program (QIP)

8. **PY 2027 QIP Measure Set:** RHA supports CMS' proposals to remove the Facility Commitment to Health Equity and Social Drivers of Health reporting measures from the ESRD QIP beginning with PY 2027. While the intent of these measures is valuable, they impose significant administrative burden, particularly on small and rural facilities, without corresponding payment or public reporting impact. CMS should also coordinate with other federal, state, and local agencies to ensure alignment, as continued data collection by other entities could result in unnecessary duplication or inconsistencies.

9. **PY 2028 QIP Measure Set:** CMS should finalize the proposed reduction in the Consumer Assessment of Healthcare Providers and Systems In-Center Hemodialysis (ICH CAHPS) survey length to reduce burden on patients and providers and should consider reducing the survey frequency to once per year, as twice-yearly administration limits the ability to act on results in a timely manner and adds unnecessary administrative cost. To balance this change, CMS could require facilities to conduct an internal patient experience survey in the alternate half of the year, with an attestation of completion submitted through the End Stage Renal Disease Quality

Reporting System (EQRS). Additionally, CMS should ensure nephrologist contributions are appropriately captured in the revised measure, either through updated question design or clearer attribution within the facility care team.

10. **RFI on Topics Relevant to ESRD QIP:** RHA offers detailed comments on the use of health information technology (IT) in dialysis facilities and on the adoption of new measure concepts. RHA requests CMS provide clearer guidance and more robust support, particularly for low-volume facilities and those who do not use electronic medical records (EMRs), before advancing Fast Healthcare Interoperability Resources (FHIR) based digital quality reporting in the ESRD QIP. CMS should ensure any new requirements do not compound existing reporting burdens or data accuracy challenges already experienced by providers. RHA recommends CMS focus future ESRD QIP measures on areas within dialysis facilities' control and avoid holding them accountable for patient behaviors or outcomes largely influenced by external factors, particularly in areas like well-being, nutrition, physical activity, and CKD detection, which are often shaped by systemic barriers and responsibilities better suited to other parts of the care continuum.

ESRD Treatment Choices (ETC) Model

11. **Termination of the ETC Model:** RHA supports CMS' proposal to finalize the termination of the ETC Model, as it did not effectively align incentives to drive sustained improvements in home dialysis or transplant metrics and placed a disproportionate burden on providers without yielding meaningful results. Future models should incorporate lessons learned by offering targeted, adequately funded demonstrations and ensure earlier and more consistent engagement with stakeholders throughout implementation.

12. **Discussion of Hurricane Helene and the ETC Model:** While CMS did not observe a statistically significant decline in home dialysis rates following Hurricane Helene, the stability of national data masks the localized and substantial disruptions faced by providers who relied heavily on Baxter, now Vantive. CMS should further investigate facility-level impacts and explore strategies to mitigate future risks to home dialysis access, such as diversifying supply chains or establishing a national reserve.

Our detailed feedback on the CY 2026 ESRD PPS Proposed Rule follows.

CY 2026 ESRD PPS

1. CY 2026 ESRD PPS Base Rate

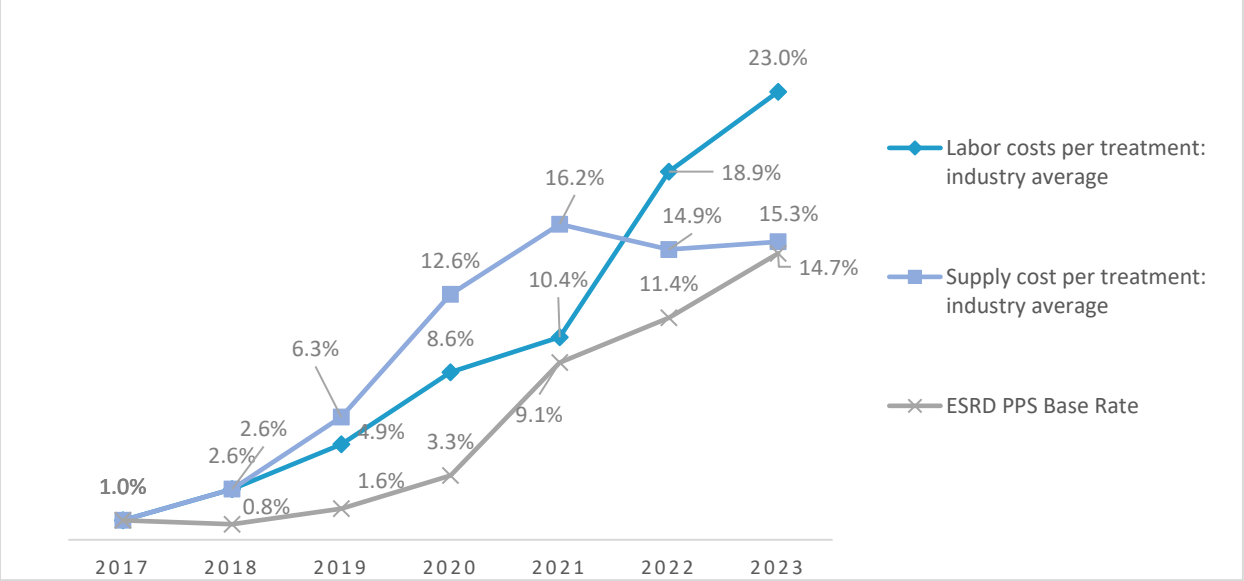
Recommendation: In light of the increasing costs per treatment incurred by facilities, we express critical concern that the proposed base rate of $281.06, a net increase of 2.7 percent ($7.24) over the CY 2025 base rate, is wholly insufficient and severely jeopardizes patient access to treatment. The RHA urges CMS to finalize a one-time, non-budget neutral increase to the ESRD PPS base rate that will more accurately and appropriately account for the increasing costs of high-quality care delivery.

Dialysis providers continue to feel the acute impact of workforce shortages and dramatic increases in supply and labor costs amplified by the COVID-19 pandemic, and yet the ESRD PPS base rate lags dramatically behind these cost increases. An RHA-commissioned analysis of dialysis facility cost report data, including preliminary 2023 industry-wide financial results, found that direct patient care labor costs

per dialysis treatment for all dialysis facilities rose by an astonishing 23.0 percent, and supply costs per treatment across all dialysis modalities rose by 15.3 percent from 2017 to 2023 (see Figure 1 below).[8] During that same time frame, dialysis providers have seen updates of only 14.7 percent to their ESRD PPS base rates – covering only 64 percent of the increase in labor costs. The ESRD PPS payment rate methodology and resulting rates have failed to keep up with increasing provider costs, and, consequently, the aggregate FFS Medicare margin was negative, at an average of -0.2 percent in 2023.[9,10]

As RHA members primarily represent small and independent facilities serving patients in rural and urban areas, they disproportionately face a significant and unsustainable gap between actual costs and reimbursement. This is in part due to their smaller facility sizes and the costs to recruit and retain essential direct patient care workers, particularly when they draw from the same labor pool as hospitals and larger health systems that can afford to pay more competitive wages. These additional costs borne by RHA member facilities are not appropriately accounted for in the ESRD PPS, and, in fact, are further exacerbated by the budget-neutral nature of the wage index (discussed below).

Figure 1: Comparison of Cumulative Growth Trends (%) in Facility Treatment Costs to ESRD PPS Base Rate, 2017-2023



Source: Analysis of 2017-2023 Medicare Cost Reports conducted by Prima Health Analytics

Throughout this period, dialysis providers, particularly those of small facilities and in rural areas, have cut costs and adjusted their care models as much as possible, but their ability to influence the market remains limited. Small and independent dialysis providers do not dominate the market and, therefore, cannot negotiate supply prices or bulk discounts for their facilities. The lack of competitors for some supplies has exasperated exorbitant and prohibitive price increases. Severe supply shortages have forced some RHA members to purchase supplies from non-contracted vendors at even higher costs, with fees for freight delivery incurred as an additional expense by facilities. These shipping costs are highest for facilities in rural locations, and, as vendors struggle to meet the consistent demand for these essential products, small

[8] Analysis of 2017-2023 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA.
[9] ESRD PPS Final Rules, CY 2017 – CY 2024
[10] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch5_MedPAC_Report_To_Congress_SEC.pdf

and independent providers are forced to pay for more frequent shipments as additional supply becomes available.

Like other providers within the healthcare community, RHA members remain dedicated to delivering the best possible care to our patients. Unfortunately, because aggregate FFS Medicare margins decidedly vary by dialysis treatment volume, many RHA members remain at a significant disadvantage. A recent MedPAC analysis showed that facilities in the lowest volume quintile reported margins below –19 percent in 2023.[11] Prolonged underpayment through the ESRD PPS has left RHA members and other rural and small providers struggling with the resulting financial and service delivery pressures. In their 2025 Data Book, MedPAC reported that dialysis facilities that closed in 2020 were more likely to be small (as measured by the number of in-center hemodialysis treatment stations). This contributed to the decline in rural dialysis capacity between 2022 and 2023.[12] Without additional funding allocated to these providers, many of whom are trying to prevent their facility doors from closing, CMS will fail to achieve its goals of managing the outsized costs of untreated chronic disease and protecting access to life-sustaining dialysis treatment for beneficiaries with ESRD. **The proposed increase of $7.24 over the CY 2025 base rate – a 2.7 percent increase – deprives the ESRD provider community of the resources needed to deliver high-quality care and threatens access to the dialysis services on which millions of Medicare beneficiaries rely.**

RHA members remain in a state of emergency, and CMS cannot wait another year to address this crisis. We continue to feel the impact of the ongoing workforce shortage, and our existing dialysis staff care for more patients and work longer and more demanding shifts than ever before. Our analysis revealed that despite the rise in direct patient care staff hourly salaries by about 13.5 percent year over year from 2021 to 2022 and an additional 3 percent in 2023, registered nurses as a percentage of direct patient care staff fell in 2023 to a 5-year low.[13] Numerous dialysis units have been forced to cap admissions due to limited personnel, requiring hospitals to delay discharge until they can find outpatient dialysis care for their patients. At times, hospitals are discharging patients without securing outpatient dialysis, forcing patients to seek dialysis treatment through expensive and otherwise unnecessary emergency room visits. The impact of inadequate funding within the ESRD PPS has expansive effects on the rest of the healthcare system. Absent sufficient funding, additional dialysis facilities may need to cease operations, further limiting access to life-sustaining dialysis treatments.

It is important to reiterate that the implications of an inadequate base rate extend beyond Medicare fee-for-service reimbursements. MA plans and other payers set their reimbursement rates for most small and independent providers based on the ESRD PPS base rate, often excluding many of the patient and facility-level adjustments offered in the ESRD PPS. This further reinforces the need for CMS to set an ESRD PPS base rate that accurately reflects current labor and supply costs.

We know that small, medium, independent, and hospital-based dialysis facilities – many of which are RHA members – care for a disproportionate number of underserved individuals. An RHA-commissioned analysis showed that in 2020, these types of organizations made up nearly all (97 percent) of dialysis

[11] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch5_MedPAC_Report_To_Congress_SEC.pdf
[12] https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf
[13] Analysis of 2017-2023 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in August 2024.

groups serving the highest concentration of low-income beneficiaries.[14] The RHA applauds CMS' commitment to prioritizing access in all aspects of healthcare delivery, including access to high-quality healthcare. However, many policies in the ESRD PPS disadvantage facilities that need the support most. Put simply, CMS must ensure that the ESRD PPS provides incentives for small and independent dialysis facilities to continue to serve these extremely vulnerable patient populations. Otherwise, patient access and choice in dialysis care will be further threatened.

CMS faces a significant decision point at this moment: the agency must either fund dialysis providers in a way that appropriately addresses the reality of the current market, or see dialysis clinics, especially small and independent facilities, shut their doors. To ensure that dialysis providers can continue delivering high-quality care amidst the persistently high costs of labor and supplies, **the RHA again calls on CMS to use its existing authority to establish a temporary, non-budget neutral adjustment to the ESRD PPS base rate.** The RHA understands that this is not a customary practice for CMS, but these extraordinary times call for extraordinary measures. In the CY 2024 ESRD PPS final rule, CMS explained that the larger-than-normal forecast errors in CY 2021 and CY 2022 were "largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 [public health emergency (PHE)]."[15] This conclusion further supports a one-time adjustment to the ESRD PPS to ensure the base rate does not continue to lag behind amidst the ongoing effects of these unprecedented market pressures that we see today. The Social Security Act authorizes CMS to "include such other payment adjustments as the Secretary determines appropriate," and nothing in this section requires the adjustments to be budget neutral or otherwise limited.[16] CMS has used its authority in the past to create the Transitional Drug Add-on Payment Adjustment (TDAPA) as well as a home dialysis training add-on payment, neither of which is budget neutral. In CY 2025, CMS again exercised this authority to introduce the non-budget neutral post-TDAPA payment adjustment.

CMS must take meaningful action under its existing authorities to course-correct the ESRD PPS base rate, address the astounding cost increases that facilities face, and help preserve patients' access to needed dialysis care. Dialysis providers, especially smaller and independent facilities, desperately need additional funds beyond those that CMS has proposed if they are to continue providing care to their patients. We adamantly urge CMS to meet this moment and adequately adjust the ESRD PPS base rate.

2. Market Basket

Recommendation: RHA urges CMS to establish an ESRD Market Basket Forecast Error Adjustment to ensure dialysis providers are not financially disadvantaged by market basket forecasting errors.

CMS proposes to use the 2020-based market basket as finalized in CY 2023 to compute the CY 2026 market basket increase in an effort to reflect the most recent and comprehensive data available. Unfortunately, the 2020 cost report data CMS used to inform the proposed CY 2026 ESRD PPS market basket update is outdated and inaccurate, considering today's dramatically different economic climate. While the RHA supports the utilization of a more recent estimate of the market basket percentage increase if available

[14] Based on study by Dobson DaVanzo & Associates commissioned by RHA, which analyzed 2020 Medicare claims for ESRD Treatment Choices (ETC) model participants. Low-income beneficiaries were defined as those who are dually eligible for Medicare and Medicaid as well as receiving the Part D Low Income Subsidy. Highest concentration dialysis groups were those serving the highest decile (in this case over 63 percent of their total Medicare patient panel) of low-income beneficiaries.

[15] CY 2024 ESRD PPS Final Rule

[16] Social Security Act, Section 1881(b)(14)(D)(iv)

before publication of the final rule, CMS' plan to base the adjustment on data from 2020 will provide an incomplete reflection of the dire circumstances in which dialysis providers currently find themselves.

As CMS stated in the proposed rule, the ESRD market basket was designed to "reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services."[17] As we noted above, costs of labor and supplies are increasing at overwhelming and unsustainable rates that are woefully and consistently underrepresented in the ESRD market basket. According to MedPAC, the increase in the cost per treatment noted above is attributable to the growth in labor and capital costs in this period, which was substantially higher compared with these categories' historical cost growth.[18] The ESRD PPS rates have not kept up with the increasing provider costs and, consequently, the aggregate FFS Medicare margin fell from 2.3 percent in 2021 to –0.2 percent in 2023.[19,20] CMS' proposed market basket increase of 1.9 percent once again falls far short, jeopardizing the quality of care to which ESRD beneficiaries will have access in the coming years.

In the CY 2023 ESRD PPS proposed rule, we saw CMS' application of the 2020 ESRD market basket adjustments on the prior year and projected market basket updates. Notably, this showed that there have been historic underestimations of the finalized market basket increases for which the ESRD PPS has not adequately addressed. While we recognize that updates to the ESRD market basket are set prospectively, and some degree of forecast error is thus inevitable, dialysis facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors.

As we saw during the COVID-19 Public Health Emergency (PHE), unanticipated price fluctuations often result in differences between the actual increases in prices faced by dialysis providers and the forecast used in calculating the update factors. **To safeguard against these discrepancies, the RHA again urges CMS to establish an ESRD Market Basket Forecast Error Adjustment** in keeping with the policy afforded to SNFs since 2003.[21] The forecast error would be determined for the most recent year for which historical data is available by comparing the projected market basket increase in a given year with the actual market basket increase in that year and, if the forecast error exceeds a certain threshold (e.g., 0.5 percent for SNFs), CMS would adjust the ESRD market basket for the following year by the error percentage.

Applying this logic to the proposed CY 2026 market basket updates, we see that CMS significantly underestimated the market basket in CY 2021 and CY 2022. CMS finalized a market basket increase of 2.4 percent in the CY 2022 ESRD PPS final rule, yet the historical data showed that the actual market basket should have been 4.5 percent, or an increase of 2.1 percent, after updating to the proposed 2020 market basket methodology.[22] Between CY 2021 through CY 2022, the two years where the market basket was underestimated by greater than 0.5 percent, the market basket was underestimated by about a combined 3.3 percent. Figure 2 below provides a summary of this data. Applying the Forecast Error Adjustment beginning in CY 2026 would add a meaningful increase to the ESRD PPS base rate and bring the payment system more in line with actual experience.

Figure 2: Summary of Finalized Market Basket Adjustments vs. Revised Market Basket Updates, 2020-2025

[17] CY 2026 ESRD PPS Proposed Rule
[18] https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_Ch5_MedPAC_Report_To_Congress_SEC.pdf
[19] *Ibid.*
[20] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch5_MedPAC_Report_To_Congress_SEC.pdf
[21] CY 2004 SNF Final Rule
[22] Table 8, CY 2023 ESRD PPS Proposed Rule

Year	Finalized Market Basket (%)	Historical 2020-based ESRD Market Basket (%)
CY 2020	2.0	1.9
CY 2021	1.9	3.0
CY 2022	2.4	4.5
CY 2023	3.0	2.8
CY 2024	2.1	2.0
Cumulative Growth	11.4	14.2
Cumulative Adjustment for CY 2021 and CY 2022	**3.3%**	

Source: CY 2021 – CY 2025 ESRD PPS Final Rules

It is for this reason that RHA continues to advocate strongly that CMS implement a Forecast Error Adjustment for all ESRD PPS facilities in CY 2026, reconciling the cumulative difference in targeted versus actual market basket updates accumulated since 2020. As noted earlier, this approach is not novel. CMS has introduced a forecast error adjustment policy into previous programs, including SNFs, to adjust for incorrectly estimated projections in the market basket updates. When CMS first introduced the Forecast Error Adjustment for SNFs, the agency explicitly determined that this type of adjustment would "not be providing a source of new industry funding. Instead, we are correcting an under forecast of pricing levels that resulted in lower payments than we would otherwise have made if actual, instead of forecast, data were used."[23] In addition, the agency retroactively calculated the adjustment of rates going back to 1998 (when the SNF PPS was established) and applied the adjustment to FY 2004 SNF rates.

In the CY 2024 ESRD PPS final rule, CMS responded to stakeholder calls for a forecast error adjustment explaining that the cumulative under-forecast of the SNF market basket increases "was not due to a PHE as occurred with the ESRD PPS's under-forecast in recent years," and that this was an issue that only SNFs were experiencing at the time.[24] CMS finalized a forecast error adjustment for the SNF payment system due to the "rapid increase in the price of labor" and because CMS "concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs."[25] While the forces driving the under-forecast of the ESRD PPS market basket today may differ from those impacting the SNF market basket in 2003, the outcomes on providers are presenting the same. <u>The ESRD PPS continues to overlook and leave unaddressed the significant shortfalls experienced during the PHE.</u> To protect dialysis providers against the rapid increase in the price of labor and to improve payment accuracy under the ESRD PPS, we again ask that CMS establish an ESRD Market Basket Forecast Error Adjustment which, according to section 1395rr(b)(F)(i)(I) of the Social Security Act, appears to be well within CMS' existing statutory authority.

3. ESRD Wage Indices

<u>Recommendation</u>: CMS should revisit the current ESRD wage index methodology to evaluate how accurately it reflects the true labor costs of providing dialysis care, particularly the training, staffing, and care coordination demands required under the Conditions for Coverage.

We appreciate CMS' receptiveness to feedback from RHA and other stakeholders regarding the need for a wage index that is based on the experience of ESRD facilities and the agency's attempt to meet this need through the new wage index methodology introduced for CY 2025. In previous comment letters RHA has

[23] FY 2004 SNF Final Rule
[24] *Ibid.*
[25] *Ibid.*

expressed concern that, because the current ESRD PPS wage index is based on the IPPS wage index, which uses hospital data, the existing methodology used to construct the current ESRD PPS wage index does not accurately reflect the ESRD facility labor market. The types of labor used in ESRD facilities differ significantly from the types of labor used by hospitals, which results in relative wage values across the United States that fail to accurately match the actual relative wages paid by ESRD facilities. For these reasons, RHA has repeatedly urged CMS to develop an ESRD PPS wage index based only on data from ESRD facilities.

While generally supportive of the new ESRD-specific wage index, we have identified aspects of the methodology that are misaligned and warrant further refinement. Given the complex care and coordination responsibilities dialysis facilities now shoulder, particularly for home dialysis patients with multiple comorbidities and higher acuity levels, CMS must ensure the wage index reflects the specialized staffing, training, and clinical demands unique to the ESRD setting. As such, **we urge CMS to continue monitoring and evaluating the methodology's ability to capture the actual labor costs and conduct additional research into alternative approaches that more accurately reimburse facilities for the extensive care they provide.**

Dialysis facilities particularly experience challenges related to training nurses for home dialysis, as regulations require home dialysis nurses to have at least 12 months of general nursing experience and an additional three months of experience in the specific home modality.[26] Nurse managers, who oversee and train these staff, must meet even more rigorous standards: 12 months of clinical nursing experience plus six months of experience providing care to patients on maintenance dialysis. While RHA agrees it is important to have training standards to ensure patient safety and quality, these time-based requirements pose substantial challenges for small and independent facilities trying to recruit, train, and retain qualified staff. RHA requests CMS modify these requirements to focus on clinical competency rather than time served. Our members report that nurses are generally trained on in-center hemodialysis in about 10 weeks, while patients often require just one week of instruction to safely perform peritoneal dialysis at home. A competency-based approach would preserve patient safety by ensuring staff have the proper skills to deliver and train patients on home dialysis, while still expanding access to home dialysis, especially in rural areas. This approach would relieve providers of burdensome and outdated staffing constraints that fail to reflect the practical realities of care delivery today.

Additionally, relying on Bureau of Labor Statistics (BLS) data presents limitations. Because BLS data is not stratified by health care setting, it fails to capture the wage dynamics specific to ESRD facilities. This is particularly problematic given the increasingly specialized training and broader care responsibilities dialysis staff are expected to fulfill under the Conditions for Coverage, especially in home dialysis programs. These responsibilities go far beyond the provision of dialysis. Dialysis staff often serve as de facto care coordinators, especially in rural communities or home settings, managing patients with complex needs such as ventilator support and navigating across healthcare settings. However, current reimbursement—particularly under the ESRD-specific wage index—fails to reflect these expanded roles or the training required to fulfill them. If CMS expects dialysis facilities to assume these broader roles, then payment policy must support them through accurate labor cost adjustments and the ability to bill for care coordination outside the dialysis bundle.

[26] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-G/part-494/subpart-D/section-494.140

Results from an RHA-commissioned analysis indicate that CMS' new methodology will have variable impact on dialysis providers and may inadvertently harm the very facilities in desperate need of greater support. Our analysis found that under the updated methodology, roughly a quarter of all dialysis facilities are projected to see payment reductions in 2025, with 969 facilities, about 13 percent of all facilities, anticipated to lose more than 2 percent of payments.[27] When comparing the impact of the updated and legacy methodology, within industry segments, hospital-based facilities, LDOs, and medium dialysis organizations (MDOs) would fare better under the new methodology, while small and independent facilities would fare meaningfully worse.[28] Among RHA members, the majority of whom are small and independent providers, 31 percent of facilities are projected to see payment reductions, with most of these anticipated to lose more than 2 percent of payments.[29] According to our findings, urban facilities – many of whom serve a disproportionate share of underserved beneficiaries – will see a reduction of $8 million under the new methodology.[30,31]

As noted throughout this comment letter, RHA members sustain care to some of Medicare's most vulnerable beneficiaries and cannot risk losing additional revenue under this new methodology. These payment reductions compound the financial strain already experienced by dialysis providers due to rising supply costs, staff shortages, and expanded care responsibilities. We fear that this methodology will fail to accurately reflect the costs dialysis providers face and instead further exacerbate the existing reimbursement insufficiencies under the ESRD PPS felt most acutely by non-LDOs. For these reasons, **we ask that CMS continue to monitor the updated wage index methodology to ensure it fully captures the complexity of care provided by dialysis facilities, the training they are required to deliver to staff, and the standards under which they must operate.** Without adequate reimbursement, dialysis providers will struggle to meet growing clinical and care coordination demands, ultimately impacting patient outcomes.

4. Outlier Policy

Recommendation: The RHA supports CMS' proposal to decrease the MAP and FDL amounts for both pediatric and adult patients in CY 2026 as a means to more effectively achieve the 1.0 percent outlier target.

The ESRD PPS outlier payment policy is a CMS-designed adjustment created to protect ESRD facilities from financial losses due to unusually high treatment costs. RHA commends CMS for the outlier policy methodological changes finalized in CY 2023 that allowed CMS to achieve the 1.0 percent outlier target for the first time in several years. As CMS acknowledges again in this proposed rule, this came after years of the outlier payments consistently landing below the target of 1.0 percent of total ESRD PPS payments, resulting in significant underpayments to ESRD facilities. Between CY 2019 and CY 2023 alone, the outlier policy has resulted in over $158 million in critically important Medicare dollars designated for the ESRD PPS outlier pool but not ultimately released to dialysis facilities. RHA was pleased to see CMS attain the 1.0 percent target in CY 2023 but remains concerned that, without further intervention, outlier payments will once again drop below the target.

Figure 3: Historic Accounting of Outlier Target vs. Outlier Payment Amounts, 2019-2023

[27] Analysis of legacy and proposed ESRD PPS wage index methodologies conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in August 2024.
[28] *Ibid.*
[29] *Ibid.*
[30] *Ibid.*
[31] *Ibid.*

Year	Projected Total Payments for ESRD Services	Outlier Target (%)	Outlier Target ($)	Actual Outlier Payment (%)	Actual Outlier Payment ($)	Amount Withheld from PPS
CY 2019	$10.6 B	1.0%	$106 M	0.5%	$53.0 M	$53.0 M
CY 2020	$10.3 B	1.0%	$103 M	0.6%	$61.8 M	$41.2 M
CY 2021	$9.3 B	1.0%	$93 M	0.4%	$37.2 M	$55.8 M
CY 2022	$8.8 B	1.0%	$88 M	0.9%	$79.2 M	$8.8 M
CY 2023	$7.9 B	1.0%	$79 M	1.0%	$79 M	$0.0 M
CY 2024*	$8.1 B	1.0%	$81 M	0.8%	$64.8 M	$16.2 M
TOTAL			**$469 M**		**$375 M**	**$175 M**

*Preliminary data

Source: CY 2020 – CY 2026 ESRD PPS Proposed Rules

RHA supports CMS' proposal to reduce the Medicare Allowable Payment (MAP) and Fixed Dollar Loss (FDL) thresholds for both adult and pediatric patients in CY 2026, which is projected to significantly increase the number of patient months qualifying for outlier payments. CMS estimates that the share of qualifying adult patient months would double from 7.05 percent in CY 2025 to 14.16 percent in CY 2026, while pediatric patient months would rise from 6.09 to 7.05 percent, marking a critical step toward maintaining the outlier payment's 1.0 percent funding target.

This improvement builds on CMS' CY 2023 methodological updates, which enabled the outlier policy to finally meet its 1.0 percent target. RHA commends CMS for taking these data-driven steps to recalibrate MAP and FDL thresholds based on more recent claims data and real-world experience. Small and independent dialysis facilities have borne the brunt of high-cost cases without adequate compensation under the outdated outlier model, and the proposed changes would better account for the financial risks these providers assume when delivering complex care.

That said, RHA continues to urge caution around proposals to expand the definition of outlier-eligible services to include additional renal dialysis drugs and biological products. We share stakeholder concerns that such an expansion could distort the intended purpose of the outlier payment as a stop-loss mechanism for unexpectedly high-cost care and, paradoxically, increase the FDL threshold so much that fewer claims would qualify. As CMS observed in CY 2025, this would disincentivize facilities from offering costly but necessary services if they cannot reliably recoup those costs—thereby undermining both clinical outcomes and policy objectives.

For these reasons, **we support CMS' proposed CY 2026 reductions to MAP and FDL thresholds as an important advance in targeting resources toward the highest-need patients**. However, we encourage CMS to continue evaluating structural reforms outside of the outlier framework to support long-term coverage of new, high-cost drugs—particularly through improvements to the post-TDAPA policy, which remains insufficient in its current form.

5. Changes to the TDAPA Eligibility Policy

Recommendation: RHA supports CMS' proposal to establish a three-year eligibility window from the date of FDA approval for TDAPA applications submitted on or after January 1, 2028. This policy change aligns TDAPA with the existing TPNIES timeframe and provides manufacturers with a clear, reasonable timeline to seek transitional payment while maintaining the integrity of the policy's intent to support truly new and innovative therapies.

The TDAPA plays a vital role in supporting access to new renal dialysis drugs and biological products by providing temporary, additional payment until the product is fully incorporated into the ESRD PPS bundled rate. CMS' current regulatory language, however, only specifies that a drug must have received FDA approval on or after January 1, 2020, to be eligible for TDAPA and does not define when a product is no longer considered "new." This creates ambiguity and potential inconsistency in application of the policy.

RHA supports CMS' proposal to clarify that TDAPA eligibility is limited to drugs and biological products for which an application is submitted within three years of FDA approval. This clarification reflects a balance by acknowledging the time and resources required for manufacturers to bring products to market, while reinforcing that TDAPA is intended to serve as a temporary bridge for the adoption of recently approved therapies.

This change is also consistent with the eligibility timeframe used in the TPNIES policy and would promote greater consistency and predictability across CMS' ESRD transitional payment programs. In practice, manufacturers typically prepare for launch well in advance of FDA approval, and a three-year window provides ample opportunity to seek TDAPA without delaying innovation or patient access. Moreover, by applying this policy only to applications submitted on or after January 1, 2028, CMS ensures a smooth transition and avoids retroactive disruption for drugs already in the pipeline.

For these reasons, **RHA supports finalizing this proposal as an important refinement to the TDAPA policy that strengthens its alignment with CMS' broader innovation goals while preserving program clarity and fiscal integrity.**

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

Recommendation: RHA supports CMS' proposal to finalize the Non-Contiguous Area Payment Adjustment (NAPA) for CY 2026 but strongly recommends implementing it as a non-budget neutral adjustment to fully reflect the elevated non-labor costs incurred by ESRD facilities in these geographies. Additionally, CMS should closely monitor supplier pricing and cost escalation trends across all regions to guard against cost inflation and ensure payment adjustments remain grounded in actual cost differentials.

RHA appreciates CMS' ongoing efforts to account for geographic cost variation within the ESRD PPS and supports the creation of the Non-Contiguous Area Payment Adjustment (NAPA) as an important step toward addressing long-standing concerns about the adequacy of payments to ESRD facilities in Alaska, Hawaii, and the U.S. Pacific Territories. CMS' own analysis shows that ESRD providers in these areas face non-labor costs up to 56 percent higher than those in the contiguous United States, driven by unique logistical challenges, including higher shipping costs, limited access to supplies, and geographic isolation.

The proposed increases—up to 25 percent for the non-labor portion of the ESRD PPS base rate—appropriately reflect these elevated cost burdens and will help sustain access to dialysis care in high-cost, low-density regions. However, **RHA urges CMS to finalize NAPA without applying budget neutrality, as doing so would dilute the financial impact of this policy and shift the cost burden onto other facilities already operating under narrow margins**. Facilities serving remote populations should not be penalized through downward adjustments elsewhere in the system when their cost structure is fundamentally different.

In addition, CMS should closely monitor supplier pricing trends across all geographies, not just in NAPA-designated areas. Stakeholders have raised concerns that policy-driven adjustments (like those

introduced in the ETC model) can unintentionally signal to suppliers an opportunity to raise prices. This risk is particularly acute in non-contiguous regions, where fewer supplier options and longer supply chains limit provider leverage. CMS should be vigilant in identifying signs of cost inflation or price gouging and consider alternative safeguards or transparency mechanisms to ensure these payment adjustments benefit patients, not intermediaries.

Lastly, while the focus of NAPA is on non-contiguous areas, providers in certain parts of the contiguous U.S. also face significant transportation, tariff, or logistics-related cost increases. RHA encourages CMS to monitor cost escalation trends broadly and assess whether other PPS adjustments or regional multipliers are warranted in future rulemaking.

Payment for Renal Dialysis Services Furnished to Individuals with AKI

Recommendation: RHA requests that CMS revisit the AKI payment rate methodology to ensure it fully reflects the higher costs of providing dialysis to patients with acute kidney injury (AKI), particularly given the increased frequency of monitoring, individualized care, and clinical oversight required across care settings.

RHA appreciates CMS' ongoing efforts to extend access to dialysis care for Medicare beneficiaries with AKI and supports the continued alignment of the AKI payment rate with the ESRD PPS base rate. However, the costs associated with treating AKI patients are often significantly higher than those of patients with ESRD, particularly due to the increased intensity of clinical oversight, individualized treatment plans, and more frequent laboratory monitoring required to preserve renal function and prevent progression to ESRD.

For example, AKI patients frequently require 24-hour urine collections and other diagnostic evaluations on a weekly basis, which is far more frequently than monthly testing protocols common for ESRD patients. Additionally, in both home and SNF settings, AKI patients require more hands-on care, nursing time, and nephrologist involvement to monitor for signs of renal recovery or deterioration. The American Society of Nephrology recommends patients with AKI have a Comprehensive Interdisciplinary Patient Assessment monthly, which is only completed annually for ESRD patients.[32,33] This assessment requires input from, at a minimum, a physician, registered nurse, social worker, and dietician.[34] These patients often present with multiple comorbidities and complex clinical profiles, demanding a more resource-intensive care model across all settings.

While the proposed CY 2026 AKI payment rate of $281.06 reflects a 2.7 percent increase over CY 2025, RHA remains concerned that applying the same payment methodology used for ESRD patients does not fully account for these unique clinical and operational demands. We urge CMS to revisit the AKI rate-setting methodology and explore mechanisms to recognize these cost differentials, either through a targeted adjustment or supplemental payment reflecting the higher acuity of this population.

RHA also reiterates concerns previously raised in response to the CY 2025 ESRD PPS proposed rule regarding the budget neutrality adjustment associated with the extension of the home dialysis benefit to AKI beneficiaries. While RHA supports offering AKI patients access to home dialysis and related training,

[32] ASN Kidney Health Guidance on the Outpatient Management of Patients with Dialysis-Requiring Acute Kidney Injury, May 2025.
[33] 42 CFR § 494.80
[34] *Ibid.*

applying an add-on payment adjustment for training services on a budget-neutral basis risks reducing the base payment for all AKI dialysis treatments. Rather than implement training-related payment reductions based on modeling assumptions, we encourage CMS to collect and evaluate actual CY 2025 utilization data for AKI home dialysis services. A data-driven approach would better inform payment policies, support accuracy in rate-setting, and avoid unintended disincentives for offering home dialysis to AKI patients. A premature rate reduction may discourage facilities from treating AKI patients or offering home dialysis altogether, especially small and rural facilities already operating within narrow margins.

In short, while RHA supports CMS' broader goal of expanding access to home dialysis and maintaining parity across treatment modalities, we urge the agency to revisit the AKI payment rate methodology to ensure it captures the true cost of care. CMS must balance payment accuracy with its policy goals to protect provider sustainability and ensure access for this vulnerable patient population.

ESRD Quality Incentive Program (QIP)

1. PY 2027 ESRD QIP Measure Set

Recommendation: RHA supports CMS' proposal to remove the Facility Commitment to Health Equity reporting measure from the ESRD QIP beginning with PY 2027. The measure imposes a significant administrative burden, particularly on small and rural dialysis facilities, without corresponding impact on payment or public reporting. RHA encourages CMS to coordinate with federal, state, and local agencies to ensure that data collection efforts are aligned and non-duplicative.

RHA appreciates the intent behind the Facility Commitment to Health Equity measure and recognizes the value of efforts that promote access to care across the dialysis community. However, as CMS itself acknowledges in the proposed rule, this measure imposed significant administrative burden on dialysis facilities without accruing benefits to patients. Continuing to require data collection under these circumstances would impose an undue administrative burden, especially for small and rural facilities that often lack dedicated administrative capacity, without delivering actionable insights or improvements in care.

Several RHA members have noted that although many facilities already integrate these practices into their operations, the formal reporting requirements introduced unnecessary complexity and duplicated efforts already captured through other quality improvement initiatives. Additionally, continued data collection by ESRD Networks or other entities outside of CMS may lead to conflicting requirements and confusion for providers. CMS should work closely with those entities to ensure that reporting policies are harmonized, reducing burden and maintaining clarity for dialysis providers.

Recommendation: RHA supports CMS' proposal to remove the Screening for Social Drivers of Health and the Screen Positive Rate for Social Drivers of Health reporting measures from the ESRD QIP beginning with PY 2027. These measures introduce redundant administrative tasks without contributing to improved patient outcomes.

RHA members are deeply committed to supporting patients' social needs through established care management practices, including quality of life (QoL) assessments and the ongoing work of dedicated social workers. These supports are already embedded in the ESRD care model and are not dependent on CMS-imposed reporting requirements. The addition of these measures into the QIP framework added administrative burden without clear benefit.

RHA also notes that the proposed removal of these measures appropriately reflects provider feedback received since their adoption in CY 2024. The goals of screening for social drivers, such as housing, food insecurity, or transportation needs, are already reflected in standard care practices across many dialysis facilities. Requiring formal reporting on these efforts is redundant and risks diverting limited resources away from direct patient care. Instead of creating additional check-box requirements, CMS should focus on strengthening interdisciplinary care teams and supporting community-based partnerships that directly address social needs.

2. PY 2028 QIP Measure Set

Recommendation: RHA supports CMS' proposal to reduce the length of the ICH CAHPS survey beginning with PY 2028 as an important step toward minimizing survey fatigue and easing administrative burden on dialysis providers. However, CMS should also consider reducing the survey frequency from twice annually to once per year and ensure that the role of nephrologists is appropriately captured in the revised measure, either through direct survey questions or clearer attribution within the facility care team construct.

RHA appreciates CMS' efforts to streamline the ICH CAHPS survey, particularly with the proposed removal of 23 questions that are not essential to performance measurement or public reporting. Shortening the survey to 39 questions represents meaningful progress in addressing longstanding concerns around survey fatigue and declining response rates among in-center hemodialysis patients. Providers also welcome the administrative relief associated with shorter surveys, particularly given the time and cost associated with vendor administration, including mailings, follow-up calls, and data processing.

That said, RHA encourages CMS to go further by reducing the survey frequency from twice a year to once annually. The current biannual approach limits the ability of facilities to act on results in a timely or meaningful way, as data from the first round of surveys are often not returned until after the second round has already begun. Hospitals and other healthcare providers typically receive survey feedback much faster, and a once-yearly administration would better align with standard performance improvement cycles. Reducing frequency would also decrease administrative costs for third-party vendors and lessen patient burden without undermining the intent of the measure. CMS could consider requiring facilities to conduct an internal survey in the alternate half of the year to strike a balance between reducing administrative burden and maintaining continuous patient feedback loops. An internal survey, with attestation submitted through EQRS, would ensure that facilities remain engaged in patient experience measurement year-round while giving them the flexibility to tailor survey tools to their patient population. Several RHA members already perform additional surveys throughout the year to obtain real-time results and more immediately inform patient satisfaction efforts.

RHA is also concerned about the removal of survey questions specific to nephrologists, including the standalone nephrologist rating item and the Nephrologists' Communication and Caring (NCC) multi-item measure. Nephrologists are central to dialysis care and should not be omitted from the patient experience measurement framework. If CMS moves forward with the current question set, it should revise survey language to explicitly reflect nephrologist involvement within the "care team" construct, ensuring their contributions are evaluated and visible within overall facility scores. Without this clarity, a critical component of patient care may go unmeasured, misrepresenting the comprehensive experience of dialysis patients.

For these reasons, **RHA supports the intent and direction of CMS' proposed changes but urges further refinement to reduce survey burden, improve data usability, and maintain the clinical integrity of the ICH CAHPS measure.**

RFI #1: Advancing Digital Quality Measurement in the ESRD QIP

RHA appreciates CMS' interest in advancing interoperability through FHIR-based data exchange and supports the long-term goal of improving data quality, accessibility, and integration across health systems. However, CMS must ensure that any new reporting requirements do not compound the significant data access, interoperability, and reporting challenges dialysis providers already face under the ESRD QIP. We are interested in learning more about the recently announced CMS Interoperability Framework and encourage CMS to seek to align broader interoperability efforts with requirements related to digital quality measurement.

RHA members use a range of health IT systems to manage patient records, with most facilities relying on certified EMRs and participating in health information exchanges (HIEs). However, technical and policy barriers, such as restrictive business associate agreements (BAAs), internal security protocols, and inconsistent EMR vendor capabilities, limit seamless data sharing. Clarity from CMS on what qualifies as "health IT," including whether platforms used by physicians for home dialysis patients are included, would be helpful as interoperability expectations expand.

While many facilities submit patient assessment data through their health IT systems, the process is not without complications. Accurate data exchange with hospitals and other providers is often impeded by issues like mismatched record sources (e.g., hospital-based dialysis units submitting the wrong patient data) or EMRs pulling inaccurate lab values (e.g., defaulting to the last result in the month). These workflow issues undermine data integrity and limit providers' ability to proactively improve quality outcomes.

Facilities also struggle with real-time access to CMS data used for QIP scoring. Providers often lack visibility into the Medicare data that CMS uses for quality assessment and cannot easily verify or correct inaccuracies. One RHA member reports a case where a provider was penalized for failing to conduct a depression screening after the patient had died, yet the EMR had no mechanism to document that exception. These examples underscore the importance of bidirectional data flow and real-time validation tools within CMS systems. CMS should provide alerts at the end of each month highlighting missing or abnormal data to help providers identify and resolve issues proactively rather than retrospectively.

Moreover, CMS recently ended the EQRS Town Hall sessions, which served as a critical support channel. Without those sessions, the EQRS help desk has become the default. This resource is often slow and unresponsive and often leads to providers being referred to outdated manuals or waiting weeks for issue resolution. **RHA strongly encourages CMS to restore these collaborative Town Hall forums and invest in additional support mechanisms, particularly for low-volume and rural facilities that may not have the IT infrastructure or staffing to implement new interoperability requirements.** Additionally, CMS could consider an add-on payment or grant support for facilities without EMRs to help them adopt compliant solutions.

RHA also urges CMS to shift some of the reporting burden from providers to the EMR vendors themselves. Many members report feeling responsible for ensuring systems perform to CMS standards, despite having limited control over system architecture. Greater accountability for vendors and more explicit CMS guidance on technical expectations would help address this imbalance.

In summary, **RHA urges CMS to approach FHIR-based reporting requirements with caution, centering any new policies around feasibility, vendor accountability, real-time validation tools, and targeted provider support.** A collaborative, incremental approach will be essential to ensure successful adoption while protecting providers from unintended administrative and financial burden. RHA requests that any new requirements be accompanied with corresponding payment updates to adequately support the successful implementation of the measure.

RFI #2: Measure Concepts under Consideration for Future Years

RHA appreciates CMS' efforts to explore meaningful quality improvement opportunities across the ESRD landscape and welcomes the opportunity to provide feedback on the measure concepts under consideration. **As CMS looks to expand the scope of the ESRD QIP, RHA urges the agency to prioritize measures that are within the control of dialysis facilities, do not impose disproportionate administrative or financial burden, and are supported by clear, actionable data infrastructure.**

Interoperability

RHA agrees that advancing interoperability is critical, particularly to improve care transitions between hospitals and dialysis facilities and to better coordinate the longitudinal care of patients with chronic kidney disease. However, many interoperability challenges are rooted in federal policy and EMR vendor limitations, not dialysis provider behavior. For example, facilities often do not receive timely hospital discharge information, making it difficult to reconcile medications or understand recent clinical events. **CMS should focus any interoperability measure on system-level readiness and infrastructure, rather than penalizing providers for factors beyond their control**. Federal leadership is needed to require vendor interoperability and ensure platforms used across the healthcare continuum, including home dialysis care tools, are fully integrated.

Well-being

While RHA supports holistic, patient-centered care, dialysis facilities should not be held accountable for patient well-being outcomes that occur outside the treatment setting and beyond provider control. Patients' emotional health, social connection, and life satisfaction are critically important, but they are shaped by a complex array of social, economic, and behavioral factors that dialysis facilities are not equipped or funded to address. **If CMS wishes to include well-being measures in the QIP, they must be appropriately scoped (e.g., tracking whether a well-being assessment was offered, rather than scoring based on outcomes) and CMS must provide adequate reimbursement or flexibility** to bring in additional supports like behavioral health providers or care navigators.

Nutrition

RHA recognizes the importance of nutritional support for dialysis patients and is supportive of the robust dietitian engagement already required under current Conditions for Coverage. Registered Dietitians (RDs) meet with patients regularly, educate families, and provide comprehensive dietary guidance tailored to each dialysis modality. However, RHA cautions against holding facilities accountable for patient behavior beyond the clinic, such as dietary choices made at home or in nursing facilities where renal diets are not enforced. **CMS should focus any future nutrition measures on whether nutritional counseling is offered, not on patient adherence or outcomes that facilities cannot control**. Rewarding education and patient engagement, rather than penalizing facilities for non-compliance, would better align with the realities of outpatient dialysis care.

Physical Activity

Encouraging physical activity for dialysis patients is important, but dialysis clinics are not rehabilitation facilities and often lack the staff, equipment, and regulatory authority to promote exercise safely during treatment. Past attempts to incorporate exercise (e.g., stationary bikes during dialysis) have been problematic, requiring physician orders and leading to complications such as infiltrated access sites. Instead of adding physical activity measures to the QIP, **CMS should explore ways to connect patients to external resources like physical therapy, or allow providers to bring in ancillary services, such as cardiology, psychology, or diabetes education, by expanding billing flexibility in the dialysis setting**. Any physical activity-related measures should reflect referral and education efforts, not facility-level responsibility for patient exercise behavior.

Chronic Kidney Disease (CKD)

Efforts to encourage early detection and treatment of CKD are essential, but such measures should target primary care providers and upstream clinicians, not dialysis facilities. RHA members report that patients often arrive in dialysis clinics with little to no prior nephrology engagement, sometimes crashing into dialysis at stage 5 with no prior referral. While dialysis facilities do play a role in CKD education, this occurs after ESRD onset, and holding dialysis clinics accountable for late referrals or lack of upstream intervention misplaces responsibility. **CMS should consider quality measures aimed at primary care or accountable care organizations (ACOs) that incentivize timely nephrology referrals based on clinical indicators such as lab values.** For dialysis providers, CMS might consider a process measure related to CKD education, if such education is delivered early in care and is properly reimbursed.

RHA encourages CMS to pursue quality measures that reflect what dialysis facilities can control and are resourced to support. Many of the proposed measure concepts, while well-intentioned, risk burdening dialysis providers with accountability for upstream, systemic issues without corresponding flexibility, resources, or reimbursement. CMS should ensure any new measures are developed in partnership with providers, are supported by accurate and timely data systems, and promote improved patient outcomes without creating undue administrative or operational strain.

ESRD Treatment Choices (ETC) Model

As submitted in previous comment letters, RHA supports the intent of the ETC model to increase rates of home dialysis and kidney transplants for Medicare beneficiaries with ESRD. However, successful participation in the ETC model has required dialysis facilities to make costly, fundamental, and time-consuming care changes in order to avoid substantial potential payment reductions under the model based on patient choices that extend beyond dialysis facility control. For many RHA member facilities, this has made model participation increasingly challenging and has negatively impacted their ability to initiate or expand access to home dialysis.

1. **Termination of the ETC Model**

Recommendation: RHA supports CMS' proposal to finalize the termination of the ESRD Treatment Choices (ETC) Model, which failed to meaningfully advance home dialysis and transplant outcomes and placed a disproportionate burden on dialysis providers without delivering corresponding benefits. Future alternative payment models should incorporate lessons learned from ETC by focusing on clear, targeted goals, ensuring adequate financial support for implementation, and engaging stakeholders earlier and more consistently throughout model development and execution.

RHA appreciates CMS' commitment to advancing innovation in kidney care through value-based models. However, the ETC Model did not achieve its intended impact, and **we support CMS' proposal to terminate the model effective December 31, 2025**. Despite covering nearly 30 percent of Hospital Referral Regions nationwide, the model failed to demonstrate sustained improvements in key metrics, including home dialysis adoption, transplant waitlisting, and living donor transplantation rates.[35]

A core issue with the ETC Model was its misaligned incentives and lack of operational flexibility. For example, when patients transitioned between Traditional Medicare and Medicare Advantage, ETC performance metrics were affected unevenly, making it difficult for providers to reliably track progress or influence outcomes. Facilities also reported that when patients moved to home dialysis, their exclusion from the in-center denominator made performance metrics appear worse—creating a disincentive for the very behavior the model was intended to promote.

In addition, the bundled design of the ETC Model, which combined both home dialysis and transplant goals, was overly broad and lacked the specificity needed for targeted improvement. Transplantation falls outside of the direct control of dialysis facilities, and providers cannot influence waitlist decisions or organ availability. Future models should focus narrowly on specific care domains, like assisted peritoneal dialysis (PD), and include demonstration projects that offer financial support for caregiver engagement or supplemental home care infrastructure.

The model's operational rollout was also problematic. CMS did not adequately engage providers during the early implementation stages, missing opportunities to adjust the program based on real-world challenges. Providers reported burdensome administrative barriers, such as delays in system access, difficulty with credentialing, and a lack of timely CMS guidance, that further limited participation and effectiveness. Compounding this was the model's mandatory nature and lack of implementation flexibility during the COVID-19 pandemic, when other CMS Innovation Center models, like KCC, were given relief.

Moreover, the broader payment system continues to create structural disincentives that contradict the goals of the ETC Model. For example, the current RVU structure pays nephrologists more for initiating and managing dialysis than for delaying dialysis or supporting transplantation. While the KCC Model includes an incentive for avoiding dialysis initiation through transplant, this was not reflected in ETC, limiting alignment across models.

Finally, the ETC Model failed to account for the real resource costs of developing or expanding home dialysis programs. Many clinics simply could not afford to absorb the costs of building new home infrastructure without upfront investment or technical support. Had the model included payments for building home capacity, such as assisted PD for qualifying patients or caregiver training pilots, results may have been more favorable.

Given these factors, **RHA supports CMS' decision to end the ETC Model and encourages future models to be more focused, better resourced, and built through transparent collaboration with providers**. CMS should use the experience of ETC to design smaller-scale, better-targeted demonstrations that reward specific innovations in patient care while minimizing provider burden and ensuring a clear path to success.

2. Discussion of Hurricane Helene and the ETC Model

Recommendation: RHA urges CMS to further investigate facility-level impacts of the Hurricane Helene-related PD supply shortage and explore long-term strategies to safeguard access to home dialysis during

[35] https://www.cms.gov/priorities/innovation/data-and-reports/2024/etc-2nd-eval-rpt

future disruptions. While CMS determined that national-level data did not show a statistically significant decline in home dialysis rates following the hurricane, this aggregate view likely masks significant regional disruptions.

RHA acknowledges CMS' decision not to retroactively adjust Performance Payment Adjustments (PPA) under the ETC Model for MY7 due to the timing of the proposed rule and lack of statistically significant national data on home dialysis declines following Hurricane Helene. However, national-level data fails to reflect the localized and severe impacts experienced by many dialysis providers who relied heavily on Baxter, which supplies approximately 60 percent of the U.S. market for IV fluids and PD solutions.

Following the October 2024 hurricane, Baxter halted new PD starts and did not fully restore production until mid-February 2025. In the interim, some facilities were unable to start new home dialysis patients altogether, and others were forced to transition existing home patients back to in-center treatment. One provider reported nearly 80 patient transitions during this time. While some facilities adapted creatively, others faced significant operational and clinical barriers. The lack of statistically significant decline in aggregate PD utilization is, in part, a reflection of the extraordinary flexibility and improvisation by dialysis providers, not an indication that no harm occurred.

Importantly, the underlying risk remains: overreliance on a single supplier leaves the dialysis ecosystem vulnerable to future shocks. Even outside of this crisis, the PD supply market is showing signs of instability. Baxter has since opted not to renew contracts for certain dialyzers, and other vendors are exiting the market in search of more profitable opportunities, further reducing competition and raising concerns about market concentration.

CMS, as part of HHS more broadly, should consider using the lessons from Hurricane Helene to advance broader policy solutions that ensure resilient, diversified supply chains for critical dialysis products. This could include:

- Establishing a national reserve of PD and dialysis-related supplies,
- Providing emergency flexibilities or relief mechanisms for facilities affected by supply disruptions,
- Encouraging competition through payment and regulatory incentives for new suppliers to enter the market, and
- Incorporating guardrails in value-based payment models, like ETC, to account for force majeure events that impact provider performance but are outside their control.

Should additional data become available, such as internal facility-level impacts from providers like DCI or Fresenius, **RHA requests CMS should remain open to revisiting its decision not to adjust PPA 7 performance metrics retroactively**, especially if localized supply chain failures are shown to have impaired access or quality of care.

Closing

In conclusion, the RHA again wishes to thank you for the opportunity to comment on CMS-1830-P. We look forward to working with CMS to clarify and improve these proposals for CY 2026 and explore new reimbursement methodologies in the future that are better suited for ESRD care. If you have any questions concerning our comments, please do not hesitate to contact me at rbomstad@wregional.com, or RHA Executive Director William Poirer at wpoirier@renalhealthcare.org.

Sincerely,

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