August 18, 2022

The Honorable Chiquita Brooks-LaSure
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-1768-P)

Dear Administrator Brooks-LaSure:

We write today to urge CMS to take action to protect access for the vulnerable Medicare beneficiaries that rely on life-sustaining dialysis treatments as it works to finalize policies in the CY 2023 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). The intense stress of the healthcare worker crisis and supply chain challenges, along with the fatigue associated with the COVID-19 Public Health Emergency (PHE), has pushed the dialysis provider community, particularly small and independent facilities, to a breaking point.

The Renal Healthcare Association (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 both free-standing and hospital-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 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-1768-P).[1] The RHA appreciates CMS' proposals and requests for information to help refine the ESRD PPS to better serve some of the most vulnerable Medicare beneficiaries who rely on access to life-sustaining dialysis treatment. We believe our recommendations will help to address the workforce and funding crisis that faces dialysis providers, ensure equitable access to high quality of care, and improve patient health outcomes for the ESRD adult and pediatric patient populations – particularly those in rural areas and from economically disadvantaged communities.

In summary, we make the following specific recommendations on the proposed rule:

[1] CY 2023 ESRD PPS Proposed Rule, https://public-inspection.federalregister.gov/2022-13449.pdf

I. CY2023 ESRD PPS and Acute Kidney Injury (AKI)

1. **ESRD PPS Base Rate:** The RHA urgently requests that CMS provide a one-time, non-budget neutral adjustment to increase the ESRD PPS base rate. An average increase of 2.4 percent over CY 2022 as proposed is not nearly sufficient to cover the double-digit rise in ESRD facility costs and rising inflation.

2. **ESRD Market Basket:** The RHA urges CMS to establish an ESRD market basket forecast error adjustment policy.

3. **Wage Index Updates:** The RHA requests that CMS further update its wage index standards to align with inpatient hospital policies.

4. **Outlier Policy:** The RHA recommends that the outlier withhold be reduced to 0.5 percent so that more funding is distributed through the ESRD PPS base rate.

5. **Home Dialysis:** The RHA urges CMS to align home dialysis reimbursement with costs, including home dialysis training, to adequately fund additional growth in this treatment modality.

6. **Oral-Only Drug Transition:** If CMS incorporates oral-only drugs into the ESRD PPS bundle, the additional costs incurred by dialysis providers must be appropriately and comprehensively accounted.

II. CY 2023 ESRD Quality Incentive Program (QIP)

1. **PY 2023 QIP Measure Set and Scoring Policy:** The RHA urges CMS to suppress *all* ESRD QIP measures in PY 2023 and remove any scoring and payment requirements, given current economic conditions and workforce shortages, combined with the continued challenges of the COVID-19 PHE, consistent with the approach taken for PY 2022.

2. **PY 2025 QIP Measure Set:** The RHA recommends a number of changes to the proposed QIP measure set, including maintaining the transfusion ratio as a reporting measure, removing the hypercalcemia measure entirely (instead of changing to reporting), and including the proposed COVID-19 healthcare personnel vaccination metric as part of Dialysis Facility Compare (as opposed to the ESRD QIP).

3. **Revisions to QIP Reporting Measure Domains and Measure Weights:** RHA supports the proposed Reporting Measure Domain but requests that CMS maintain the Reporting Measure Domain at 18 percent of the total QIP score. Furthermore, the RHA urges CMS to re-base performance for the first full year after the PHE to accurately and adequately account for the impact of the COVID-19 pandemic on both patients and providers.

III. ESRD Treatment Choices (ETC) Model

1. **CY 2023 ETC Model Payment Penalties:** The RHA urges CMS to postpone payment penalties under the ETC model due to the ongoing impacts of the COVID-19 PHE.

2. **Home Dialysis Rate Definition:** To ensure fair participation of rural, small, and independent providers in the ETC model, the RHA recommends revisions to the home dialysis rate policy and to the definition of aggregation groups.

3. **Kidney Disease Education (KDE) Services:** The RHA respectfully requests that KDE coinsurance waivers be extended across the entire ESRD PPS and expanded such that eligible home dialysis nurses and Certified Nephrology Nurses (CNNs) would also be able to deliver KDE.

IV. Requests for Information

1. **Addressing Transitional Drug Add-on Payment Adjustment (TDAPA) Payment Issues:** The RHA supports the establishment of a straightforward add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after their TDAPA period ends.

2. **Health Equity Issues within ESRD PPS with a Focus on Pediatric Payment:** The RHA offers detailed recommendations to advance and invest in health equity under the ESRD PPS and to improve payment accuracy of pediatric reimbursement to more accurately reflect the distinct costs associated with delivering high-quality care to pediatric patients.

3. **Quality Indicators for Home Dialysis Patients:** The RHA recommends that CMS revise its QIP methodology related to home dialysis programs and disagrees with the inclusion of home dialysis measures in the QIP. The RHA suggests strategies whereby CMS can more effectively monitor and assess the quality of home dialysis care delivered and broaden equitable access to home dialysis across different ESRD patient populations.

4. **Potential Future Inclusion of Two Social Drivers of Health Measures:** The RHA supports the intent of the two social drivers of health measures proposed but recommend that CMS not add these measures to the QIP. Instead, RHA recommends leveraging already collected SDOH data sources to alleviate additional reporting burden on dialysis providers.

CY 2023 ESRD PPS and Acute Kidney Injury (AKI)

1. **CY 2023 ESRD PPS Base Rate**

Recommendation: In light of the supply and labor cost increases to dialysis facilities, we wish to express critical concern that the proposed base rate of $264.09, an increase of only 2.4 percent, 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.

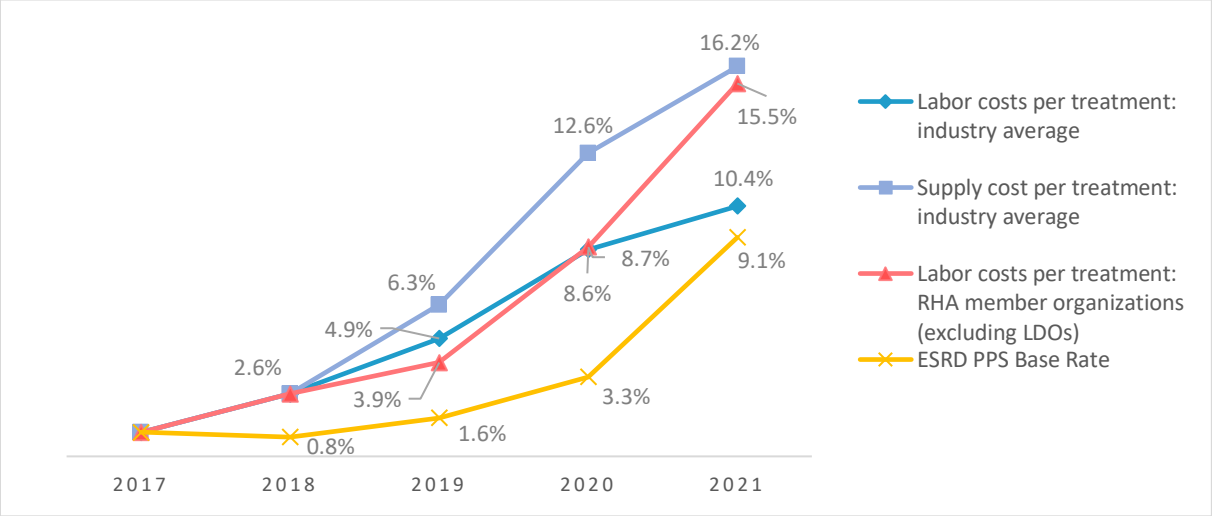
The COVID-19 pandemic has created significant and lasting effects on dialysis facility expenses – through both staffing and supply costs – which the ESRD PPS does not appropriately reflect. While supply and staffing shortages existed before the onset of COVID-19, the pandemic's extraordinary strain on America's healthcare system has dramatically exacerbated the workforce emergency and supply chain challenges in many RHA-member facilities across the US. Importantly, economic data indicate that these supply cost increases are not temporary, and these changes to labor rates are unlikely to ever reverse course.

As the healthcare community struggles to regain its footing amidst the ongoing COVID-19 public health emergency, dialysis providers continue to feel the acute impact of workforce shortages and dramatic increases in supply and labor costs, and yet the ESRD PPS base rate lags behind the cost increases. According to an RHA-commissioned analysis of 2017-2021 dialysis facility cost report data, direct patient care labor costs per dialysis treatment for all dialysis facilities rose by a 10.4 percent, and supply costs per treatment across all dialysis modalities rose by an astonishing 16.2 percent from 2017 to 2021 (see

Figure 1 below).[2] During that same time frame, dialysis providers have seen updates of only 9.1 percent to their ESRD PPS base rates between 2017 and 2021. It is clear that the ESRD PPS rates have not kept up with the increasing provider costs.[3]

Notably, these costs are not distributed equally across the dialysis provider community. RHA members experienced a staggering 15.5 percent increase in labor cost growth during this period. This means that RHA members experienced a 50 percent increase in the rate of labor growth over this period compared to the industry as a whole. RHA members primarily represent small and independent facilities serving patients in rural and urban areas. This disproportionate increase in labor costs is likely due to the smaller facility sizes and the costs to recruit and retain essential direct patient care workers, particularly when drawing from the same labor pool as hospitals and larger health systems which can afford to pay more competitive wages. While the industry faced an on-average increase of 16.2 percent in supply costs per treatment between 2017 and 2021, independent dialysis units report an astounding 37.2 percent increase in supply costs, with hospital-based dialysis units and small dialysis organizations also reporting significant increases within this period (21.9 and 19.3 percent, respectively).[4] 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, 2017-2021



Source: Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics

Throughout this period, dialysis providers, particularly those in small and rural areas, have cut costs and adjusted their care model as much as possible, but in general their ability to influence the market is 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 further solidified 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

[2] Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in July 2022.
[3] ESRD PPS Final Rules, CY 2017 – CY 2021
[4] Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in July 2022.

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 and independent providers are forced to pay for more frequent shipments as more supply becomes available. After multiple years of ESRD PPS rates not keeping up with costs, RHA member organizations are at a critical breaking point and require adequate funding to continue caring for their patients. **The proposed increase of $6.19 over the CY 2022 base rate – a mere 2.4 percent increase – is woefully inadequate in this time of economic and staffing instability and may ultimately threaten the access to, and quality of, care for individuals relying on Medicare for their dialysis services.**

In February 2022, RHA conducted a survey of its members[5] to better understand the issues and impact of staffing shortages within the dialysis provider community. Initial findings included the following:

1) Half of respondents (51 percent) reported shortages of over 10 percent for dialysis nurses and technicians.
2) Two-thirds (66 percent) are using travel staff to fill patient care staffing vacancies, at considerably higher costs than pre-pandemic rates.
3) The majority (63 percent) of respondents noted an increase in staff turnover rates compared to pre-pandemic rates.
4) Most (80 percent) of respondents reported the need to increase salaries to retain staff (43 percent report increasing wages by over 10 percent).

We also know that the staffing and supply cost increases experienced to date are expected to continue, the consequences of which will extend well beyond 2022. According to a recent survey of RHA members, RHA members reported a 9 percent increase in labor costs per treatment during the first quarter of 2022 (January – March), compared to labor costs during the first quarter of 2021. Cumulatively, RHA members experienced an 18 percent increase between 2019 and 2022. In addition, RHA members report that the conditions reported in February continue to get worse: now nearly two-thirds (60 percent) report staffing shortages of over 10 percent (as compared to half reported earlier) and all (vs. 80 percent) respondents report having needed to increase salaries to retain dialysis staff, with 73 percent of respondents reporting wage increases of over 10 percent.[6] CMS cannot wait another year to address this crisis.

Dialysis providers have reached a state of emergency and, by necessity, are sounding the alarm. RHA members are feeling the impact of the staffing shortage, and the existing dialysis staff are caring for more patients and working longer and more demanding shifts. 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. Without adequate funding, dialysis facilities may need to cease operations, further limiting access to live-sustaining dialysis treatments.

It is important to note that the implications of an inadequate base rate extend beyond Medicare fee-for-service reimbursements. Medicare Advantage plans and other payors also set their reimbursement rates

[5] The February 2022 survey released by RHA had 35 respondents, representing 2.6 million dialysis treatments in 2021.

[6] RHA member survey conducted in August 2022. Respondents reported data on labor costs from January through March (quarter 1), years 2019 through 2022. Respondents provided data on staffing levels and facility wages.

for most small and independent providers based off the ESRD PPS, often times excluding many of the adjustments offered in the ESRD PPS. This further reinforces the need for CMS to set a base rate that accurately reflects current labor and supply costs.

Many of the same small and independent dialysis facilities described above also care some of our nation's most vulnerable patients. 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. As discussed later in our response to the Request for Information, we report RHA research that small, medium, independent, and hospital-based dialysis facilities, including many that are members of RHA, are disproportionately serving the most disadvantaged patient populations. Our analysis showed that these types of organizations made up nearly all (97 percent) of dialysis groups serving the highest concentration of low-income beneficiaries.[7]

The RHA applauds CMS' commitment to centering equity in all aspects of healthcare delivery, including access to high-quality healthcare. However, many policies in the ESRD PPS disadvantage facilities that most need the support. 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: CMS must either appropriately fund dialysis providers that addresses the reality of the current market or see dialysis clinics, especially small and independent facilities, shut their doors to some of Medicare's most vulnerable patients due to inadequate reimbursement under the ESRD PPS. The recommendations within the CY 2023 ESRD PPS proposed rule to rebase and revise the market basket as well as tweak the wage index proposals are insufficient actions to address the critical funding needs that RHA members face. As we enter our third year of this pandemic, we must think collectively and creatively about how we continue to support Medicare ESRD beneficiaries as the challenges facing our healthcare providers continue to intensify.

One such way to ensure that dialysis providers can continue delivering high-quality care amidst the persistently high costs of labor and supplies would be for **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. The Social Security Act authorizes CMS to "include such other payment adjustments as the Secretary determines appropriate" and nothing in this section requires that the adjustments be budget neutral or otherwise limited.[8] Historically, CMS has used its authority in the past to create the Transitional Drug Add-on Payment Adjustment (TDAPA) and also a home dialysis training add-on payment that are not budget neutral.

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

[7] 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.

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

providing care to their patients. We adamantly urge CMS to meet this moment and adequately adjust the ESRD PPS base rate.

The recommendations made throughout this letter address critical actions that must be taken immediately to stave the current reimbursement crisis faced by dialysis providers. Looking to the future, however, it is clear that the ESRD PPS payment system is not meeting the existing and ever-changing needs of providers and requires reform. Over the longer term, RHA would like to work with CMS to refine and update the ESRD PPS to adequately meet the needs of dialysis providers in a more nimble and timely way to better accommodate necessary payment increases to dialysis facilities due to market changes, pandemics, or other forces we cannot anticipate today. Our members' experiences indicate that the current payment system does not accord payments with the actual cost of care delivery, particularly for the very medically and socially complex patients. RHA provided significant comments on priority considerations for a reformed payment system as part of its comment letter in last year's rulemaking process. The RHA appreciates and looks forward to the opportunity to work with the agency to improve the ESRD PPS to ensure that payments align with the costs necessary to deliver high-quality care to all Medicare beneficiaries with ESRD.

2. Market Basket

<u>Recommendation</u>: RHA supports CMS' proposed changes to the ESRD market basket but urges CMS to establish an ESRD Market Basket Forecast Error Adjustment to ensure that dialysis providers are not financially disadvantaged as a result of market basket forecasting errors.

The RHA appreciates CMS' proposal to rebase the ESRD market basket and update the labor-related share using 2020 data to reflect the most recent and comprehensive data available. Unfortunately, the 2020 cost report data informing the proposed CY 2023 ESRD PPS market basket update is outdated and inaccurate considering the dramatically different economic climate we are experiencing today. The RHA supports the utilization of the most recent data available (for example, a more recent estimate of the market basket and/or productivity adjustment) before the publication of this final rule, but this data, too, will provide an incomplete reflection of the dire circumstances in which dialysis providers currently find themselves. As we noted above, costs of labor and supplies are increasing by overwhelming and unsustainable rates. CMS' proposed market basket increase of 2.4 percent falls far short, jeopardizing the quality of care to which ESRD beneficiaries will have access in the coming years.

In Table 8 of the proposed rule, we see CMS' application of the proposed 2020 ESRD market basket adjustments on prior year and projected market basket updates. Notably, this table shows 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, <u>dialysis facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors.</u>

As we've seen during the PHE, unanticipated price fluctuations may 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 urges CMS to establish an ESRD Market Basket Forecast Error Adjustment**, in keeping with the policy afforded to Skilled Nursing Facilities (SNF) since 2003.[9] 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

[9] CY 2004 SNF Final Rule, https://www.govinfo.gov/content/pkg/FR-2003-08-04/pdf/03-19677.pdf

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 2023 market basket updates, we see that CMS significantly underestimated the market basket in CY 2021. CMS finalized a market basket increase of 1.9 percent in the CY 2021 ESRD PPS final rule, yet the historic data showed that the actual market basket should have been 3.0 percent, or an increase of 1.1 percent, after updating to the proposed 2020 market basket methodology.[10] Applying the Forecast Error Adjustment beginning in CY 2023 would bring the payment system more in line with actual experience, adding 1.1 percent to the ESRD base rate in CY 2023, equivalent to an estimated increase of $2.90 in the base rate.

As it relates to CY 2022 projections, the finalized CY 2022 market basket increase was 2.4 percent, but latest projections in the CY 2022 market basket indicate that a more accurate market basket update is 4.5 percent.[11] This is a staggering shortage of 2.1 percent in the market basket, or an added $5.28, that should be flowing to ESRD facilities as part of the ESRD PPS base rate. Over CY 2021 and 2022, the market basket has been underestimated by about a combined 3.2 percent. Figure 2 below provides a summary of this data. Together, the errors in these forecasts are equivalent to an increase of $8.18 over the CY 2023 ESRD PPS base rate, and under current policy, one that CMS is expecting ESRD facilities to carry with no recourse for retroactive adjustments.

Figure 2: Summary of Finalized Market Basket Adjustments vs. Revised Market Basket Updates, 2020-2023

Year	Finalized Market Basket (%)	Proposed 2020-based ESRD Market Basket (%)[12]	Difference (%)
CY 2020	2.0	1.9	-0.1
CY 2021	1.9	3.0	+1.1
CY 2022 (estimate)	2.4	4.5	+2.1
CY 2023 (estimate)	TBD	2.8	N/A
		Cumulative Adjustment	**+3.1**

Source: CY 2021 – CY 2023 ESRD PPS Final Rules

It is for this reason that RHA advocates strongly that CMS implement a Forecast Error Adjustment for all ESRD PPS facilities in CY 2023, reconciling the cumulative difference in targeted versus actual market basket updates for the length of the pandemic (2020-2022). As noted earlier, this approach is not novel. CMS has introduced a forecast error adjustment policy into previous programs, including SNFs, to adjust for incorrect estimated projected in the market basket updates. According to section 1395rr(b)(F)(i)(I) of the Social Security Act, we have every indication that establishing an ESRD Market Basket Forecast Error Adjustment is well within CMS' existing statutory authority.

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".[13] In addition, the agency retroactively calculated the adjustment of rates going back to 1998 and applied the adjustment to FY 2004 SNF rates. Incidentally, CMS states that the major reason that the SNF market basket forecast was

[10] Table 8, CY 2023 ESRD PPS Proposed Rule
[11] CY 2022 ESRD PPS Final Rule; Table 8, CY 2023 ESRD PPS Proposed Rule
[12] Table 8, CY 2023 ESRD PPS Proposed Rule
[13] FY 2004 SNF Final Rule, https://www.govinfo.gov/content/pkg/FR-2003-08-04/pdf/03-19677.pdf

under-forecast during this period was that "wages and benefits for nursing home workers increased more rapidly than expected."[14] Certainly, ESRD facilities are facing a very similar experience and should be granted parity in policies offered to SNFs, including a Market Basket Forecast Error Adjustment in the CY 2023 proposed ESRD PPS base rates, retroactive to CY 2021 and applied annually thereafter.

3. Wage Index

<u>Recommendation</u>: The RHA appreciates the proposals to update the wage index and further requests that CMS update its wage index standards to align with inpatient hospital policy.

The RHA thanks CMS for the proposed increase to the wage index floor from 0.500 to 0.600 for CY 2023 onward and appreciates the agency's efforts to more accurately capture the current economic climate in the updated labor-related share (LRS) of the ESRD PPS base rate from 52.3 to 55.2 percent.

Amidst the inflationary pressures and workforce shortages discussed in previous sections, we agree that labor-related expenses are accounting for an increasingly large part of the ESRD PPS base rate and, as discussed above, we expect this trend to continue. Small and independent ESRD facilities typically have higher labor costs than larger dialysis organizations because of the generally higher proportion of skilled labor used in care delivery. The use of more highly skilled labor translates to overall greater costs of care, including training and actual care delivery, for small and independent facilities. ESRD facility cost reports from 2021 confirm this trend (see Figure 3 below): organizations in RHA that were not large dialysis organizations (or non-LDOs) reported a 25 percent higher average direct patient care labor costs per treatment and a 14 percent higher average hourly salary than LDOs and non-RHA members.[15] Similarly, facilities in rural regions have difficulty attracting labor, which is more challenging now than ever before given the critical shortage of nursing staff available. Moreover, if rural facilities are not able to find permanent staff locally, they must pay the associated travel costs and wages for travel time for staff traveling from units outside of the area qualified to treat patients. Some providers informally report that the hourly cost of travel staff now averages *five times greater* than a full-time staff member hired in a dialysis facility. These staffing challenges raise labor costs for rural providers, increasing their overall costs to provide high-quality care for patients.

Figure 3: Comparison of Average Labor Costs Between RHA and Non-RHA Members, 2021

Provider Type	Average Direct Patient Care Labor Costs Per Treatment	Average Direct Patient Care Hourly Salary
RHA members (excluding LDOs)	$112.20	$31.94
Non-members (including LDOs)	$89.80	$27.92

Source: Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics

Because wage index updates are budget-neutral in the short-term, the only facilities that benefit from the updated LRS are those ESRD facilities with a higher wage index. Conversely, lower wage index facilities will now experience lower relative payments, due to a higher proportion of their base rate being adjusted based on the wage index and will thereby be equipped with fewer resources with which to provide dialysis care. Under the Inpatient Prospective Payment System (IPPS) Prospective Payment

[14] Ibid.

[15] Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in July 2022.

System, hospitals with a wage index less than or equal to 1 are paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.[16] CMS has clearly recognized this issue in other programs and CMS should consider applying a similar mitigation strategy within the ESRD PPS to provide relief to low wage facilities.

By way of an example of the implications for dialysis providers, in Figure 4 below, we have outlined one hypothetical ESRD facility and the impact of both the increase in the LRS and a lower wage index. According to this proposed rule, the 2.4 percent productivity-adjusted market basket increase should add $6.19 to the ESRD PPS base rate for CY 2023. After adjusting for the LRS and wage index updates proposed, this facility's base rate increase of $1.50 (or 0.7 percent) falls far short when compared to the 2.4 percent increase CMS has proposed.

Figure 4: Impact of Proposed CY 2023 Labor Related Share and Wage Index Updates on Hypothetical ESRD Facility

Year	ESRD PPS Base Rate	Labor-Related Share	Wage Index	Labor-Related Portion	Non-Labor-Related Portion	Wage-Adjusted ESRD PPS Base Payment
CY 2022	$257.90	52.3%	0.7612	$102.67	$123.02	$225.69
CY 2023 (proposed)	$264.09	55.2%	0.7469	$108.88	$118.31	$227.19
Change	***$6.19 (2.4%)***	*2.9%*	*-0.0143*	*$6.21*	*-$4.71*	***$1.50 (0.7%)***

Source: CY 2022 ESRD PPS Final Rule; CY 2023 ESRD PPS Proposed Rule

To achieve CMS' stated goal of mitigating instability and avoiding significant and unpredictable payment reductions for facilities, the RHA reiterates that increases to the LRS and changes to the wage index are not sufficient vehicles for providing additional, necessary funds to providers, especially those in rural areas. In analyzing CMS' Facility-Level Impact File, we see that rural providers are facing a -0.3 percent reduction on average in their wage index when comparing 2022 and 2023 rates and that only 6 percent of rural providers are expected to have a wage index update greater than one.[17] This evidence supports a growing concern that the current wage index system perpetuates and exacerbates the disparities between high and low wage index facilities. CMS has acknowledged the shortcomings of the wage index system in other programs, having introduced policy solutions like the low wage index hospital policy. This policy, finalized by CMS in the FY 2020 IPPS final rule, provides increases to wage index for hospitals that fall in the lowest quartile of wage index values.[18] Like with the differential LRS noted above, CMS should deploy this strategy to provide some needed relief to the lowest wage index dialysis facilities under the ESRD PPS.

Finally, RHA members remain concerned that the current wage index policy does not provide parity between dialysis facilities and hospitals, despite being subject to the same wage index. **RHA requests that CMS apply the same wage index standards to dialysis facilities as offered to inpatient hospitals.** As stated above, inpatient hospitals have access to a different labor-related share based on their wage index, as well as additional relief for the lowest wage index hospitals. Furthermore, hospitals have the benefit of ensuring their Core-Based Statistical Area (CBSA) wage index is not lower than their statewide rural average. Despite CMS' proposed wage index floor increase to 0.6, dialysis providers in some urban

[16] FY 2020 IPPS/LTCH PPS Final Rule, https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-16762.pdf
[17] RHA analysis of CY 2023 Facility-Level Impact File.
[18] FY 2020 IPPS/LTCH PPS Final Rule, https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-16762.pdf

low-wage areas will remain at a significant disadvantage compared to their hospital counterparts, as hospitals located in these areas either receive the increased statewide rural average wage index or have the ability to reclassify to an adjacent area with a potentially higher wage index. To remain competitive with hospitals and recruit and retain high-quality clinical staff, dialysis facilities must be able to have access to the same wage index standards as inpatient hospitals.

4. Outlier Policy

Recommendation: **The RHA urges CMS to reduce the percentage of payments allocated for the outlier pool from 1 percent to 0.5 percent in order to shift more resources to providers through their regular reimbursement process**.

The RHA appreciates the updates proposed by CMS in this latest rulemaking to try to improve the accuracy of the outlier policy methodology. As CMS acknowledges in this proposed rule, outlier payments have consistently landed below the target of 1.0 percent of total ESRD PPS payments. This concern is made evident by the disparity between targeted and actual outlier payments reported consistently over the past several years, as shown in Figure 5. During this timeframe, the outlier policy has resulted in over $150 million in critically important Medicare dollars designated for the ESRD PPS outlier pool but not ultimately released to dialysis facilities.

Figure 5: Historic Accounting of Outlier Target vs. Outlier Payment Amounts, 2019-2021

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	$41.2M
CY 2021	$9.3 B	1.0%	$93 M	0.4%	$37.2 M	$55.8M
TOTAL			**$302 M**		**$152.0 M**	**$150.0 M**

Source: CY 2020 – CY 2022 ESRD PPS Final Rules

We also understand that CMS is bound by statute to implement an outlier policy, so the agency has limited authority to terminate the outlier policy without Congressional action.[19] The RHA recognizes that by updating the outlier policy and associated methodology, CMS may move closer to meeting the agency's total outlier payment target. However, with the projected $8.2 billion in Medicare FFS for ESRD services in CY 2023, falling short by even 0.2 percent would deny dialysis providers $16.4 million in ESRD PPS expenditures. Even if CMS were to achieve the full 1 percent outlier target, this $82 million in ESRD expenditures would be withheld from dialysis providers until a later date when outlier payment adjustments were processed and distributed.

As staffing shortages and inflationary pressures drive expenses to unprecedented and unsustainable levels, dialysis providers cannot afford to wait for future outlier payment adjustments, nor can they risk losing any more ESRD reimbursement should CMS once again fall short of their target. **As such, RHA recommends that CMS reduce the percentage of payments allocated for the outlier pool from 1 percent to 0.5 percent to ensure the maximum amount of up-front funds flow to providers during this time of crisis.** Further in support of this change, CMS has already proposed to update the methodology

[19] Social Security Act, Section 1881(b)(14)(D)(ii)

for calculating the fixed-dollar loss (FDL) amount in this proposed regulation, and so the agency could further adjust its methodology to accommodate an updated 0.5 percent payment target.

5. Home Dialysis

Recommendation: CMS should evaluate and provide more appropriate reimbursement for the actual costs of providing and growing home dialysis services, including home dialysis training costs, particularly in small and independent facilities.

The RHA strongly supports expanding patient access to home dialysis and shares in CMS' understanding that this treatment modality can offer meaningful improvement in quality of life and health outcomes for ESRD patients for whom it is medically appropriate. Thus, the RHA is committed to making home dialysis more widely available to patients with severe kidney disease.

The RHA wishes to underscore many of its previous comment letters that dialysis facilities seeking to offer home dialysis services bear unique costs that the current ESRD payment system does not fully consider. With fewer resources and limited market power to negotiate, such costs generally are higher and thus more restrictive for small and independent facilities, including many members of RHA. RHA members report that home dialysis equipment and supply costs have increased between 20-30 percent in recent years, substantially limiting facilities in their ability to rent or purchase the necessary equipment and thus offer patients the ability to dialyze at home. Home hemodialysis has only three approved vendors and peritoneal dialysis has only two vendors.

This extremely limited competition in supply has driven up equipment and required maintenance costs for providers, prohibiting many facilities – particularly smaller and independent facilities – from offering home services to their patients. Under the ETC model, dialysis providers are forced to either pay the outrageous supply and equipment costs or choose to accept the payment penalties for being unable to afford home dialysis services for their patients. Moreover, certain suppliers are conditioning purchase price of home equipment and supplies on the purchase of other non-home dialysis-related supplies, leading to further expenditure increases for ESRD facilities. Finally, certain suppliers place an allocation limit on how much they will supply to certain facilities when shortages arise, effectively barring these facilities from offering home therapy to patients beyond the allocated supply amount. On top of these inflated costs, the increase in wages required to hire and retain qualified home training staff makes establishing or expanding home dialysis programs near impossible for many RHA members. As such, **CMS should evaluate and provide more appropriate reimbursement for the actual costs of providing home dialysis services, especially in small and independent facilities that must invest in the equipment and are less likely to obtain group purchasing discounts to afford it.**

In addition, dialysis training costs are not adequately reimbursed in the ESRD PPS. In 2016, CMS concluded that providers spend approximately 2.66 hours per session training patients on home therapy and, under the ESRD PPS, a separate home dialysis training add-on payment is made to providers accordingly.[20] The 2.66 hour per session value is a significant underestimation of the time that dialysis clinics allocate to training patients on home therapy today, rendering the current add-on payment vastly insufficient. Familiarizing non-medically trained and often hesitant patients with these highly complex therapies and equipment is neither a quick nor an easy task. A Technical Expert Panel convened by Dobson DaVanzo concluded that in reality, facilities spent between 7.5 and 8 hours per session to train

[20] CY 2017 ESRD PPS Final Rule, https://www.govinfo.gov/content/pkg/FR-2016-11-04/pdf/2016-26152.pdf

patients on home dialysis.[21] A training nurse often provides instructions before, during, and after a patient's treatment, taking the time necessary to ensure the patient and their caregiver are adequately prepared to safely administer dialysis at home. Given the significant discrepancy between the outdated number of training hours for which CMS reimburses facilities and the actual time required to train patients on home dialysis, **CMS should conduct an analysis to more accurately determine a more accurate number of hours per session needed for successful home dialysis training and subsequently revise the home dialysis training add-on payment amount to accurately reflect the growing cost to providers of home dialysis training services**. This analysis and resulting add-on payment should differentiate based on type of home dialysis, since patients on home peritoneal dialysis generally require more training than home hemodialysis. Lastly, patient cost-sharing requirements related to home dialysis trainings should be removed or limited in order to remove financial barriers for beneficiaries, especially those in underserved communities, and provide better access to home dialysis modalities.

The healthcare worker shortage, especially among dialysis nurses, presents a crisis for the delivery of dialysis care in general, and is further exacerbated when considering expansion of services into patients' homes. To meet existing Conditions for Coverage (CfC) requirements in §494.100 for a home dialysis program, dialysis facilities must have a registered nurse with one year of nursing experience and three months of experience working with in-facility and home dialysis modalities. In many cases, an additional registered nurse is required for oversight if the other RN is newer to home dialysis. Notably, RHA members are seeing significant competition amongst the many ESRD facilities and the impact of the ETC model has further driven down available staffing for small or independent facilities. Facilities offering home dialysis services that lose their dialysis nurses to new competitors must hire new nurses or re-train current ones at significant and at times unsustainable costs. **In light of the healthcare staffing crisis, RHA recommends that CMS evaluate the impact and feasibility of an expansion of the definition and level of experience of staff eligible to deliver home dialysis training to other trained dialysis staff.**

6. Oral-Only Drug Transition

<u>Recommendation</u>: If CMS incorporates oral-only drugs into the ESRD PPS bundle, the RHA requests that the additional costs incurred by dialysis providers be appropriately and comprehensively accounted.

The RHA appreciates CMS' efforts to improve payment for renal dialysis services under the ESRD PPS and recognizes the agency's desire to include oral-only drugs into the ESRD PPS bundle beginning in January 2025. MedPAC suggests that this policy will result in better drug therapy management for the ESRD beneficiary, expanded access to patients who lack Medicare Part D coverage, and improved provider efficiency.[22] <u>If CMS wants to see these outcomes achieved, dialysis providers need adequate financial support from CMS to implement the policy</u>.

As CMS notes in this proposed rule, ESRD facilities must make operational changes and logistical arrangements before they can furnish oral-only renal dialysis service drugs and biological products to their patients. For example, since some oral-only drugs are not administered on the in-center dialysis schedule, dialysis facilities will need to fill and distribute the medications to their patients. As a result, dialysis facilities incur additional costs that should not be theirs to shoulder, particularly not now when providers are already at a financial breaking point. As one RHA member noted, logistics involved with

[21] Dobson Davanzo Analysis of CMS Payment Setting Procedures, Underlying Data and Policy Implications, prepared for RHA in 2018

[22] March 2021 Report to the Congress: Medicare Payment Policy – MedPAC, https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/

getting ESRD drugs to a patient can be more expensive than the drugs themselves. These costs are even greater when recipients are based in rural communities, putting their providers, like many RHA members, an even greater disadvantage.

The incorporation of oral-only drugs into the ESRD PPS bundle will only be effective if facilities are equipped with the resources they need to successfully furnish these treatments to their patients. Without comprehensive support from CMS, facilities will be unable to sustain these added costs and patient access to these treatments may be compromised. **The RHA respectfully requests that CMS carefully evaluate and consider not only the costs of the drug, but also the staffing and operational costs associated with distribution of oral only drugs to ESRD patients ahead of the January 2025 deadline.**

CY 2023 ESRD Quality Incentive Program (QIP)

1. PY 2023 QIP Measure Set and Scoring Policies:

<u>Recommendation</u>: Due to current economic conditions and workforce shortages, combined with the continued challenges of COVID-19, CMS should suppress all 14 ESRD QIP measures in PY 2023, waive all payment penalties as was done for PY 2022.

RHA appreciates CMS' proposal to continue suppression of six QIP measures for PY 2023 in recognition that ESRD facilities continue to face challenges outside of their control that would limit their ability to perform on these measures. However, CMS did not propose a blanket payment penalty waiver, as was finalized in last year's rulemaking. CMS' decision to lift ESRD Quality Incentive Program (QIP) payment penalties for PY 2022 (based on activity during 2020) provided substantial relief to RHA members and flexibility to focus staffing resources on maintaining critical beneficiary access to care during the height of the COVID-19 pandemic. We recommend that CMS suppress all QIP measures for PY 2023 and again waive any payment penalties for CY 2023.

With the Biden Administration having once again extended the PHE declaration on July 15th as COVID-19 continues its spread across the US, we believe the same concerns that led CMS to finalize this policy for PY 2022 QIP remain relevant to considerations for PY 2023. We have every indication that the severe staffing and supply shortages faced by facilities in 2021 will meet the requirements of one or more of the Measure Suppression Factors finalized in the CY 2022 ESRD PPS Final rule. Of note is the Measure Suppression Factor 4 related to significant national shortages or rapid or unprecedented changes in in healthcare personnel; medical supplies, equipment, or diagnostic tools or materials; or patient case volumes or facility-level case mix. As discussed in the prior section, these shortages continued to afflict ESRD facilities and many other healthcare providers throughout 2021 and continues today.

Of the eight measures that were not proposed to suppress in this proposed rule, only three are clinical measures, meaning that they are scored under the ESRD QIP, unless otherwise waived. These measures should be suppressed in PY 2023, and all payment penalties should be waived for all measures. The three clinical measures are listed below with a description of RHA's proposed Measure Suppression Factor for each.

1) <u>Standardized Fistula Rate.</u> There has been numerous shortcomings with the delivery of vascular access that limit dialysis facilities' abilities to ensure fistula placement in suitable patients. With a shortage of healthcare personnel, dialysis facilities have experienced significant challenges getting on the schedules for vascular surgeons to do the fistula placements. In fact, some providers report seeing increases of 20-30 percent on their 90-day

catheter rates. As a result, RHA recommends applying Measure Suppression Factor 4, related to shortages in healthcare personnel.

2) Hypercalcemia. CMS proposes to convert this clinical measure to reporting in PY 2025 since the measure has topped out and that other measures of bone mineral metabolism might be better suited for the ESRD QIP. As such, it does not make sense to score facilities on this measure in PY 2023. In addition, providers report that during the PHE they have experienced shortages of medical supplies, including prescription drugs needed to treat hypercalcemia. RHA recommends that CMS apply Measure Suppression Factor 4, which accounts for significant shortages in medical supplies and other goods.

3) National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI). We additionally suggest that CMS add the NHSN BSI measure to this list of measures eligible for suppression under the Factor 3 measure suppression policy. Factor 3 accounts for rapid or unprecedented changes in clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials due to COVID-19. With respect to the NHSN BSI measure, the pandemic has created a number of challenges in care delivery and treatment related to catheter removal and fistula insertion – ultimately resulting in more catheters and increased likelihood of patient infection. Initially, the procedure was not deemed "essential," making it ineligible to be performed at the outset of the pandemic. For all of these reasons, the RHA urges that CMS apply proposed Factor 3 to make the NHSN BSI measure eligible for the proposed QIP measure suppression policy.

Given the persistent and unpredictable nature of this health crisis, along with ESRD patients' disproportionate vulnerability to COVID-19, **the RHA strongly urges CMS to continue the policy finalized in the CY 2022 ESRD PPS rulemaking to waive payment reductions on all QIP measures in PY 2023.** Since we recommend strongly that CMS suppress all measures and waive any payment penalties, we recommend that CMS similarly update its regulations at 42 CFR 413.177(a) and 413.178(h) to reflect the special scoring rule, consistent with the agency's approach in PY 2022. In addition to being consistent with the approach last year, we know that CMS has continued to waive payment penalties in other payment systems for 2023. For example, in the FY 2023 IPPS PPS final rule, CMS finalized the suppression of several measures and waived all scoring in the Hospital Value-Based Purchasing (VBP) Program noting that using only data from the unsuppressed measures would not be "an appropriate or meaningful indication of quality, [nor] would it result in nationally comparable assessment of quality of care for overall hospital performance".[23] The RHA strongly urges CMS to extend this same reasoning to the ESRD QIP and waive all payment penalties from the final rule.

2. PY 2025 QIP Measure Set:

Recommendation: The RHA recommends a number of changes to the proposed QIP measure set, including maintaining the transfusion ratio as a reporting measure, removing the hypercalcemia measure entirely (instead of changing to reporting), and including the proposed COVID-19 healthcare personnel vaccination metric as part of Dialysis Facility Compare (as opposed to the ESRD QIP).

a) Keep the Standardized Transfusion Ratio (STrR) as a Reporting Measure

The RHA remains concerned that the STrR measure is not an accurate reflection of how dialysis providers manage anemia in their patients. The STrR is based on transfusion information reported and maintained by hospitals or outpatient departments, to which dialysis facilities do not have access. Not

[23] FY 2020 IPPS/LTCH PPS Final Rule, https://www.govinfo.gov/content/pkg/FR-2019-08-16/pdf/2019-16762.pdf

only do dialysis facilities often lack access to this information, but they also have little ability to correct or implement care practices that can improve performance to reduce the number of transfusion events occurring in ESRD patients. Even if an ESRD patient receives a blood transfusion for reasons entirely unrelated to their ESRD, hospital billing departments often code transfusions as being ESRD-related. If the STrR measure were to be converted to a clinical measure, dialysis providers would be unduly and unfairly penalized for each transfusion a patient receives, no matter the underlying cause and often entirely unrelated to the care they provide. This would be especially problematic for small and independent facilities with low patient volumes and limited resources where just one infusion unrelated to dialysis care can have a significant adverse impact on a facility's QIP total performance score, jeopardizing patient access to high-quality care. For these reasons, the RHA urges CMS to keep the STrR a reporting measure only.

b) Remove the Hypercalcemia Measure from the ESRD QIP Measure Set (Instead of Converting to a Reporting Measure)

The RHA appreciates that CMS has recognized the challenges associated with the hypercalcemia measure and agrees with CMS that the measure lacks meaningful distinctions in performance as a measure of bone mineral metabolism and is an inaccurate reflection of provider care. Rather than convert the hypercalcemia clinical measure to a reporting measure beginning in PY 2025, the RHA urges CMS to remove the measure from the QIP measure set entirely. While the conversion from clinical to reporting would alleviate the measure's impact on facility QIP performance scores, eliminating the measure all together would prevent facilities from having to report on a measure that CMS and dialysis providers know lacks significance. Furthermore, as discussed above, until it's removed, the hypercalcemia measure should be suppressed while the agency explores possible replacement measures that would be more clinically meaningful for purposes of quality improvement.

c) Recommend that CMS Add COVID-19 Healthcare Personnel (HCP) Vaccination Measure to Dialysis Facility Compare, instead of the ESRD QIP

The RHA strongly supports policies and practices that protect the safety of Medicare beneficiaries with ESRD and the healthcare personnel that care for them. This includes tracking and reporting COVID-19 vaccination rates for ESRD patients and healthcare personnel at individual dialysis facilities, as we agree with CMS that having such information will better enable patients and their families to make treatment decisions that meet their individual care needs. Measures proposed for inclusion in QIP should be ones that leverage financial incentives to encourage quality improvement within ESRD facilities. Currently, under CMS' Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule, all eligible dialysis HCP have been required to be vaccinated against COVID-19 since January 4th, 2022, with protocols put in place for any employees who have received exemptions. This is not a measure that would benefit from QIP's financial incentives to change ESRD facilities' behavior.

To be clear, RHA does not disagree with the consumers having access to this measure to make informed healthcare decisions, and to that end, recommends that CMS include this measure on Dialysis Facility Compare (DFC) , instead of through the QIP infrastructure. In addition, to support DFC reporting and limit reporting burden on dialysis facilities, RHA recommends that CMS access data directly from existing National Healthcare Safety Network (NHSN) reporting methods and frequency to attain COVID-19 vaccination data among HCP in dialysis facilities.

4) Revisions to QIP Reporting Measure Domains and Measure Weights:

<u>Recommendation</u>: RHA supports the proposed Reporting Measure domain but requests that all reporting measure weights remain unchanged. RHA recommends that CMS continue to waive payment penalties throughout the PHE and use the first year after the PHE ends to re-establish benchmarks for the QIP program.

RHA appreciates CMS' efforts to create a Reporting Measure domain as part of the QIP measure set proposed for PY 2025 and has no concerns with the creation of this reporting domain. **The RHA requests, however, that the agency maintain existing measure weights for the measures that would be shifting into the Reporting Measure domain**. Currently, the existing reporting measures are worth a total of 18 percent of a provider's QIP score; CMS is proposing to reduce the measure weights in this category to 10 percent, and that even includes a score for the newly added COVID-19 healthcare personnel vaccination metric. The Reporting Measure domain should be worth at least 18 percent of the total QIP score. Providers strive to maintain high performance across all QIP measures, not just those that may impact facility payments. Reporting measures play a critical role in the high-quality care RHA members provide to their patients and the diligence with which they report these important data should not be devalued.

COVID-19 has had a profound and disproportionate impact on Medicare ESRD beneficiaries. In 2021, the nation's dialysis population shrank for the first time since the US began keeping detailed ESRD patient data.[24] While the full implications of the pandemic have yet to be quantified, evidence suggests the ESRD patient population looks dramatically different than it did three years ago. As such, the RHA recommends that CMS use the first full year after the PHE ends to re-establish benchmarks for the QIP program, rather than relying on benchmarks established pre-pandemic which are no longer comparable to current activity.

ESRD Treatment Choices (ETC) Model

The RHA strongly supports the intent of the ETC model to increase rates of home dialysis and kidney transplant for Medicare beneficiaries with ESRD. Successful participation in the ETC model requires that dialysis facilities make costly, fundamental, and time-consuming care changes in order to avoid substantial payment reductions under the model based on patient choices that are not within dialysis facility control. The RHA remains extremely concerned that this mandatory shift in provider focus presents facilities – especially small, independent, and hospital-based and rural providers with limited resources – with significant challenges, particularly amidst the ongoing COVID-19 pandemic. Beyond costly equipment and supplies, establishing a home dialysis program requires a more experienced RN, as discussed earlier. Amidst the ongoing shortage of nursing personnel, many dialysis facilities are unable to allocate nurses to home dialysis. In the wake of this ongoing crisis, to financially penalize dialysis facilities for failing to meet ETC model benchmarks is unjustifiable and will severely jeopardize patient access to treatment. Lastly, without appropriate CMS intervention, the ETC model will put small and independent facilities at even greater risk of closure and potentially lead to further consolidation in the already highly concentrated dialysis market. To mitigate these ongoing challenges and protect patient access to all care settings, the RHA offers the following recommendations:

<u>Recommendation:</u> Consistent with actions taken in other CMS programs, CMS should remove the negative payment penalties in the ETC model for CY 2023 due to the ongoing PHE.

Dialysis facilities required to participate in the ETC model began receiving payment adjustments from CMS as of July 2022 related to their performance during CY 2021. Some facilities are currently subjected

[24] 2021 USRDS Annual Data Report

to payment reductions of up to 5 percent, while others have the opportunity to earn incentive payments up to 4 percent, on top of the other reimbursement and staffing challenges discussed earlier in this letter. These payment adjustments further increase in CY 2023 based on performance in CY 2022. Furthermore, an analysis of 2019 and 2020 Medicare claims data in ETC model comparison geographic areas shows that LDOs have placed substantial resources into geographic comparison areas to raise ETC model achievement benchmarks, making it disproportionately more difficult for non-LDOs participating in the ETC model to avoid severe payment cuts.[25] These severe payment penalties, layered on top of the critical staffing and supply shortages and additional sequestration cuts, is having detrimental effects on dialysis facilities, especially small and independent facilities included within RHA.

Throughout the COVID-19 pandemic, CMS has taken meaningful action to protect some providers from assuming downside risk and has acknowledged the difficulty of performing under regular metrics during a highly irregular time. For example, CMS has provided automatic extreme and uncontrollable circumstances to clinicians required to participate in the Merit-based Incentive Payment System (MIPS), and removed negative payment adjustments during the pandemic in the Medicare Shared Savings Program to ameliorate the impacts of the pandemic. In April, CMS proposed to indefinitely delay the start of the Radiation Oncology (RO) Model in response to stakeholder calls for critical model modifications and in recognition of the unreasonable operational resources required of CMS and RO participants.[26]

CMS has not been consistent in its policies to provide protection for all provider types against negative payment adjustments, or to make meaningful policy adjustments to alternative payment models based on concerns voiced by health providers and stakeholder groups. RHA advocated strongly to postpone implementation of the ETC model, yet CMS forged ahead with the model in the midst of a global pandemic. CMS has not taken consistent or appropriate action to protect dialysis providers, and the extremely vulnerable patients they serve, from the detrimental payment cuts included the ETC model. To mitigate these ongoing challenges and protect patient access to all care settings, **CMS should remove the negative payment penalties related to any performance periods during the PHE, consistent with actions taken in other CMS programs.** In addition, CMS should retroactively reconcile any negative payment adjustments issued to providers during the second half of 2022 and beyond, and establish a 6-month waiver period after the PHE ends to ensure that dialysis providers have sufficient time to reset their operations post-pandemic and establish the necessary programs and infrastructure to succeed under the model.

The RHA applauds CMS in their decision to publish de-identified ETC model data to the ETC model website and agrees that this information will help educate the public on costs, quality of care, and ETC model participants' performance in the model. We recommend that CMS publish this information as quickly as possible after it becomes available to ETC participants. Once public, the RHA urges CMS to monitor and evaluate disproportionate impact of ETC model participation on small and independent facilities.

Recommendation: CMS should allow for flexibilities in the home dialysis rate definition to ensure rural and non-LDO providers are able to fairly participate in the ETC model.

The RHA thanks CMS for its recognition that small and independent dialysis facilities face unique challenges in achieving success under the ETC model due to resource limitations that make it difficult to

[25] Dobson DaVanzo analysis of 2019 and 2020 Medicare LDS claims data

[26] Radiation Oncology Proposed rule, published on April 8, 2022. https://www.govinfo.gov/content/pkg/FR-2022-04-08/pdf/2022-07525.pdf

initiate and maintain home dialysis programs. As RHA members and CMS work together to increase the number of Medicare ESRD beneficiaries on home dialysis, we respectfully request that **CMS allow non-LDOs to receive full credit in the Home Dialysis Rate for each referral of an ETC-participating beneficiary to a different facility with an active home dialysis program.** This policy critically helps non-LDOs without existing home programs to continue to support growth in home dialysis. We believe that a revised policy awarding full credit to non-LDOs that refer eligible patients to other facilities with home programs would increase the numbers of Medicare ESRD beneficiaries on home dialysis, achieving the goals of the ETC model and leading to improved quality of life for this vulnerable patient population.

In addition, **CMS should revise its definition of aggregation groups used to calculate the home dialysis rate to capture home dialysis provided by other affiliated ESRD facilities but located outside the hospital referral region (HRR) participating in the ETC model.**[27] As currently constructed, the ETC model aggregation groups capture home dialysis provided by another ESRD facility as long as that facility is part of the same ownership and also is located in the same HRR. On the other hand, a dialysis facility could have an affiliated facility as part of its ownership with a home program, but that affiliated facility is outside the arbitrary HRR lines. Smaller dialysis providers may have only one dialysis facility located within an ETC HRR, which provides a significant disadvantage in performance on the home dialysis metric. Given the barriers that already face small, independent, and hospital-based dialysis facilities, coupled by their mandatory participation in the ETC model, CMS should evaluate opportunities to ensure that these facilities are receiving the maximum credit for their efforts and held harmless from payment reductions under this model.

Recommendation: The RHA supports CMS' proposal to prohibit the furnishing of kidney disease patient education services by clinical staff who are leased from or otherwise provided by an ESRD facility or related entity. Furthermore, the RHA requests that KDE coinsurance waivers be extended across the entire ESRD PPS and expanded such that eligible home dialysis nurses and Certified Nephrology Nurses (CNNs) would also be able to deliver KDE.

The RHA shares in CMS' commitment to protect patients from undue influence when selecting an ESRD treatment facility. As such, the RHA supports the proposed prohibition against the furnishing of kidney disease patient education services by clinical staff who are leased from or otherwise provided by an ESRD facility or related entity.

Given the critical importance of informing patients about their kidney disease and available treatment options, the RHA respectfully requests that KDE coinsurance waivers be extended across the entire ESRD PPS. These waivers allow a broader scope of beneficiaries to have access to kidney disease patient education services, as well as greater flexibility in how the education services are delivered. In line with CMS' commitment to equitable health access, we believe that these services should be available to all ESRD PPS beneficiaries, not just those receiving care from ETC model participants.

The RHA remains supportive of CMS' earlier decision to permit "qualified staff" beyond just doctors, physician assistants, nurse practitioners, and clinical nurse specialists, to furnish KDE. This has dramatically increased patient access to information, understanding, and support as they navigate life with kidney disease. While maintaining the prohibition against clinical staff leased from or provided by an ESRD facility, the RHA requests that CMS expand KDE such that eligible home dialysis nurses and CNNs would also be able to deliver KDE services to the patients with whom they regularly interact. While protecting patients from fraud and abuse, this expansion would advance the ETC model's goal of

[27] Definition for aggregation of ESRD facilities in the ETC model is established at §512.365(b)(2)(e)(1)

increasing access to kidney disease patient education services and making beneficiaries more aware of their choices in kidney treatment modality**.**

Requests for Information

1. **Request for Information About Addressing Issues of Payment for New Drugs After Transitional Drug Add-on Payment Adjustment (TDAPA) Period Ends**

The following section is responsive to these questions in the RFI:

- *Is an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period ends needed? If so, why? What criteria should CMS establish to determine which renal dialysis drugs or biological products would be included in the calculation for an add-on payment adjustment after the TDAPA period ends?*

- *If an add-on payment adjustment for certain renal dialysis drugs and biological products in existing ESRD PPS functional categories after the TDAPA period is needed, are the methods discussed in section II.D.4 of this proposed rule sufficient to address the add-on payment adjustment?*
    - *Which method would be most appropriate?*
    - *Are there changes to the methodologies that CMS should consider to improve our ability to align payment for renal dialysis services with resource utilization?*
    - *Are there other methodologies that CMS should consider?*

The RHA strongly supports CMS' efforts to create pathways for innovative ESRD treatments. While policies like the Transitional Drug Add-on Payment Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) play a critical role, they do not provide sufficient support for the long-term adoption of innovation or inspire innovators to develop new treatments for people who require dialysis. The RHA thanks CMS for its consideration of alternative methods for applying, approving, and financing these innovative products, thereby expanding ESRD patient access to the care improvements they offer.

Recommendation: CMS should establish an add-on payment adjustment for new drugs after the TDAPA period ends to protect patient access to these innovative products.

RHA agrees that the existing funding mechanisms under the ESRD PPS are insufficient to safeguard patient access to new drugs and biological products after the two-year TDAPA period expires. The RHA therefore urges CMS to establish a post-TDAPA add-on payment adjustment for drugs in existing functional categories.

RHA appreciates the opportunity to provide comment to CMS on the various options for calculating the add-on payment and looks forward to additional specificity from CMS in order to evaluate these various options. Of the options suggested for calculating the add-on payment, RHA most identifies with the last option, which would "*only use the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA*." While other options may be a more technically sound way to construct an add-on payment estimate for the ESRD PPS, the calculation of this add-on payment must be logical and straightforward so dialysis facilities can easily understand the new drug's impact on its financial projections and encourage additional adoption of the new drug in its facilities.

We recommend that CMS use at least two full years of claims data to accurately capture product price and utilization. To do so will require an extension of TDAPA period beyond two years. The pricing

process for a new drug after the TDAPA period should not require an annual rebalancing of the whole PPS bundle. The RHA does not support adding a new drug to the ESRD bundle if it has low utilization rates (less than 5 percent of ESRD patients use it); in this case we recommend that the drug remain an add-on payment. In addition, the add-on adjustment should be updated annually based on any inflationary changes that may increase drug costs, to ensure these add-on payment amounts growth proportionally with the market.

Recommendation: CMS should reform the administration of and financial model supporting TDAPA and TPNIES in order to truly encourage innovation in the field.

Incorporating new equipment and treatments can be a challenging and time-intensive process for ESRD facilities. To ensure providers have sufficient time to integrate these innovations into their business, make informed decisions about use, and begin timely contracting with managed care payers, the RHA requests that CMS provide TDAPA and TPNIES reimbursement amounts no less than 6 months in advance of qualifying products becoming available for patient use. Furthermore, rate-setting should be better informed to more accurately reflect how and where devices will be used. For example, the $9.73 offset amount proposed for the Tablo hemodialysis system (E1629) may adequately reimburse for in-center treatments, it is not nearly sufficient to cover utilization costs for one patient dialyzing at home; one member reported anecdotally that at this offset amount, it would take a facility over 10 years to recoup the costs associated with in-home use of the Tablo system.

Lastly, and in response to CMS' recent independent dialysis facility cost report update, the RHA recommends that CMS collect both Medicare reimbursement as well as facility costs for TDAPA and TPNIES to better capture the entire impact of the drug or supply on dialysis facility finances. RHA agrees that tracking reimbursement for TDAPA and TPNIES on the cost reports will be valuable, and RHA agrees that this information would be most at a specific drug or supply level (i.e., not summarized in one line for TDAPA). The recent cost report update also requested changes retroactively to the beginning of CY 2022. Since completion of this reporting retroactively would introduce significant burden during a time where dialysis facilities are already facing staffing shortages, RHA recommends that any cost report updates begin prospectively, instead of retrospectively, as changes mid-year require facilities to revise and reclassify expenditures for costs already incurred.

Recommendation: CMS must protect access to TDAPA innovations for ESRD patients enrolled in Medicare Advantage (MA).

As the number of ESRD beneficiaries enrolled in MA plans continue to grow, CMS must ensure that MA plans do not restrict patient access to treatment innovations, such as those offered under TDAPA. Under MA plans, beneficiaries are to receive all required Medicare benefits (except hospice) through private insurers, including access to TDAPA-eligible innovations.[28] Despite this statutory requirement, MA plans do not always make separate payment for all drugs eligible TDAPA. In certain cases, RHA members have seen MA plans refuse separate payments to facilities for their provision of TDAPA-eligible drugs to ESRD beneficiaries. In other instances, lack of separate reimbursement appears due to MA plan misunderstanding that the TDAPA is a payment separate and distinct from the base rate and not included in the ESRD PPS bundle. When MA plans do not make separate payments for the often costly TDAPA-eligible drugs, they jeopardize beneficiary access to novel therapies that could improve their quality of care and health outcomes. Small and independent facilities in particular simply cannot bear the financial burden of these expensive therapies without receiving adequate reimbursement for them.

[28] CRS Report, Medicare Advantage (MA) Coverage of End Stage Renal Disease (ESRD) and Network Requirement Changes, published on January 11, 2021, https://crsreports.congress.gov/product/pdf/r/r46655

This concern becomes even more acute for these facilities in the many instances when they become burdened with the beneficiary bad debt liability associated with the provision of the TDAPA- eligible drug. As CMS encourages dialysis providers to adopt new and innovative treatments, the agency must require that all Medicare Advantage plans adequately reimburse for what may be more effective treatment and a better care experience. To prevent any delay or lag in coverage, CMS should issue guidance to MA plans to remind them of the requirements to offer all covered Medicare benefits. CMS should also provide advance notification to MA plans on the TDAPA drugs under consideration and, if approved, establish mechanisms to monitor and audit to ensure that beneficiary access to required coverage is maintained.

2. Request for Information on Health Equity Issues within ESRD PPS with a Focus on Pediatric Payment

The RHA strongly supports efforts to reduce disparities and improve equity in the delivery of care to all Medicare beneficiaries with ESRD and appreciates the opportunity to share feedback on these important issues. As CMS states in the RFI, when compared to FFS beneficiaries not receiving renal dialysis services, FFS beneficiaries receiving renal dialysis services are disproportionately young, male, disabled, Black/African American, low income (as measured by dually eligible Medicare and Medicaid status), and reside in an urban setting.[29] The COVID-19 pandemic has further exacerbated existing disparities, making the need to close the health equity gap even more urgent.

RHA welcomed the release of the President's Executive Orders in January 2021 addressing issues of health equity, and we appreciated the opportunity to participate in the Technical Expert Panel (TEP) convened by Acumen on this topic in December 2021. RHA agrees with the summary of the TEP as reported in the proposed rule, including the following key themes:

- Social determinants of health (SDOH) and geographic isolation issues contribute to increased costs for providing ESRD services that are not adequately reimbursed in the ESRD PPS.
- Disparities exist in accessing home dialysis and kidney transplants, and certain patient-level factors are considered risk factors for health disparities in ESRD treatment, such as the quality of pre-dialysis care, homeless/housing insecurity, limited English proficiency, behavioral health issues, amputation or wound care needs.
- SDOH are not reported or reimbursed in the PPS, though dialysis facilities do assess and collect SDOH information for their patients.

As RHA members interact with some of Medicare's most vulnerable patient populations on a very regular basis, we are uniquely positioned to both advise on opportunities to reduce these barriers, as well as deliver essential care to some of the nation's most vulnerable patients. 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. In looking at the distribution of low-income beneficiaries, an RHA-commissioned analysis[30] summarized in Figure 6 found the following statistics:

- Of the dialysis groups that had patient panels comprised of at least half low-income beneficiaries, 70 percent of the facilities were not part of large dialysis organizations (LDOs),

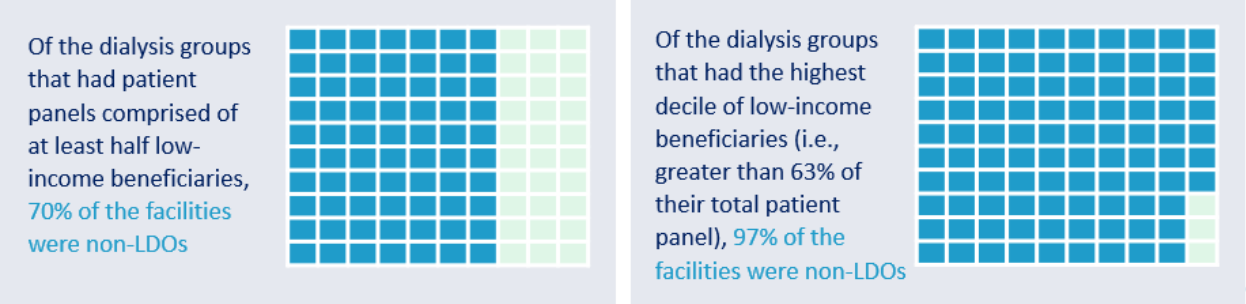
[29] Acumen Technical Expert Panel Summary Report, April 2022, https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2022.pdf

[30] 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.

including hospital-based (27 percent), medium dialysis organizations (20 percent), small dialysis organizations (12 percent), and independent organizations (11 percent).

- Of the dialysis groups that had the highest decile of low-income beneficiaries (i.e., greater than 63 percent of their total patient panel), 97 percent of the facilities were non-LDOs: 44 percent were hospital-based, 26 percent were medium dialysis organizations, 18 percent were independent, and 9 percent were small dialysis organizations. Only one LDO facility group had over 63 percent of their patient panel considered low-income. Importantly, none of these facilities were in urban areas.

Figure 6: Non-LDO Dialysis Groups Care for a Disproportionate Number of Low-Income Medicare Beneficiaries



The RHA also submitted comments in February in response to CMS' "Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities (CMS-3409-NC)" RFI, in which we outlined financial barriers for patient access to organ transplants and transplant program criteria that disadvantage patients who are lower income or face challenges related to social determinants of health. We also articulated disparities in access to home dialysis and required supports that are needed to achieve equity within this population, some of which are reiterated in our responses below.

The following section is responsive to these questions in the RFI:

- *What kind of refinements to the ESRD PPS payment policy could mitigate health disparities?*
- *Are there specific comorbidities that should be examined when calculating the case-mix adjustment that would help better represent the ESRD population and address health disparities?*
- *Are there specific subpopulations whose needs are not adequately accounted for by the current ESRD PPS payment policy?*
- *How can CMS revise case-mix categories in the ESRD PPS to better represent underserved populations?*

As discussed at great length in earlier in this comment letter, the ESRD PPS does not provide adequate reimbursement for ESRD facilities, partially due to the current staffing and economic crisis and continuation of the COVID-19 PHE. Individuals on dialysis are some of Medicare's most vulnerable patient populations, experiencing numerous comorbidities and other SDOH challenges. While the ESRD PPS base rate has increased 9.1 percent between 2017 and 2021, ESRD providers have experienced increases in patient care labor costs per dialysis treatment (10.4 percent) and supply costs per treatment

(16.2 percent).[31] **At this point, dialysis providers are in crisis, and CMS should allocate additional funding to help sustain and protect beneficiary access to life sustaining ESRD treatment. If facilities are not able to stay afloat with their current reimbursement structure, we are certain to see even more health disparities within the ESRD population.**

Notably, the costs to care for ESRD beneficiaries are not distributed equally across the dialysis provider community. RHA members experienced a staggering 15.5 percent increase in labor cost growth during this period, or a 50 percent increase in the rate of labor growth over this period compared to the industry as a whole. This increase in labor costs is likely due the smaller facility sizes and the costs to recruit and retain essential direct patient care workers. While the industry faced an on-average increase of 16.2 percent in supply costs per treatment between 2017 and 2021, independent dialysis units report an astounding 37.2 percent increase, with hospital-based dialysis units and small dialysis organizations also reporting increases within this period (21.9 and 19.3 percent, respectively).[32]

In addition, the RHA recommends that CMS model an adjustment for ESRD facilities treating a large proportion of low-income patients or patients experiencing SDOH challenges that is similar in concept to the disproportionate share hospital (DSH) payment adjustment available to hospitals under the Inpatient Prospective Payment System. A "DSH-like" payment adjustment would allow dialysis facilities who are treating beneficiaries with disproportionately elevated numbers of dual eligible beneficiaries or beneficiaries experiencing social risk factors an avenue for reimbursement to cover the additional staff time and resources needed to provide ESRD services and help to close critical social and medical care gaps.

RHA also recommends that CMS make changes to the existing facility-level adjustments in the ESRD PPS, such as the low-volume payment adjustment (LVPA) and rural adjustment. As we've commented previously, these adjustments are not adequate to address differences in costs across these various facility types. In particular, we request that CMS make modifications to the eligibility requirements for the rural adjustment to expand it to include facilities that reside in a CBSAs designated as urban, but in a zip code within that CBSA that is rural. We further suggest that CMS limit the low-volume and rural adjustment to those facilities most in need whose costs are not currently adequately covered by the adjustments – small and independent facilities, or those dialysis clinics belonging to organizations with 500 or fewer facilities. And lastly, CMS should reduce the lookback period used in the eligibility for the LVPA to two years and consider any facility that met LVPA criteria in the three-year period ahead of the PHE automatically receive LVPA until the end of the PHE.

RHA requests that CMS make refinements to the existing ESRD PPS structure based on patient-level characteristics and facility-level factors that more accurately differentiate the costs of treatment for individual patients with unique care needs. Similar to the facility-level adjustments described above, the ESRD PPS and its existing patient-level modifiers do not adequately compensate dialysis providers for increased costs associated with treating patients with SDOH challenges. RHA member facilities report that food and transportation are the biggest SDOH concerns that their patients face. Some members even reported that over 50 percent of their patients have food insecurity. A patient's lack of access to nutritious food and transportation to and from dialysis facilities and other medical appointments contributes to health disparities for these patients, but also creates enormous challenges for dialysis facilities who are caring for patients who have missed treatments or cannot sustain the diet

[31] Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in July 2022.

[32] Analysis of 2017-2021 Medicare Cost Reports conducted by Prima Health Analytics, Weymouth, MA. Prepared for RHA in July 2022.

necessary for safe dialysis. Traditional Medicare does not cover these or related SDOH services for beneficiaries, and therefore dialysis facilities must leverage their limited ESRD PPS funding to connect these patients with needed services in the community.

While disparities have been well-documented related to uptake of home dialysis, the ESRD PPS does not adequately account for expenses associated with offering home dialysis. A multitude of barriers stand between patients and their ability to make an informed decision on dialysis modality. Dialysis centers seeking to develop and sustain home dialysis programs face prohibitive equipment and supply costs, inadequate reimbursement by the ESRD PPS, and unprecedented shortages in their healthcare workforce. As discussed earlier, CMS should align home dialysis reimbursement with costs, including home dialysis training, to encourage and fund additional growth in this treatment modality. CMS should remove financial barriers associated with accessing home dialysis, such as removal or reduction of patients' required copayment for home dialysis training. Lastly, CMS should evaluate opportunities to provide financial support for staff-assisted home dialysis, so that patients who do not have access to a trained caregiver would be able to access the benefits of home dialysis.

ESRD facilities also report that activities pre-dialysis are associated with additional health disparities for patients undergoing dialysis, such as lack of adequate primary care access. Earlier detection and intervention of CKD are key to improving quality of life and patient outcomes. This is especially important for racial/ethnic minorities who are more likely to be diagnosed with CKD in the later stages of the condition which makes the disease harder to treat and worsens the prognosis.[33] Since the symptoms of CKD are non-specific and easily attributable to other diseases, primary care providers must first be better armed to detect CKD. Earlier identification of CKD is important to slow the progression of the disease and expanding access to screening must be a priority. RHA recommends adding CKD screening to the annual Medicare wellness benefit. In addition, we reiterate our recommendation to expand access to kidney disease education (KDE) to earlier stages of CKD, request that coinsurance waivers be extended across the entire ESRD PPS (outside of just the ETC model) and allow eligible home dialysis nurses and Certified Nephrology Nurses (CNNs) to deliver KDE. Teaching patients with advanced chronic kidney disease about the upcoming signs of kidney failure and dialysis treatment modalities can slow the disease's progression and help reduce the risk of "crashing" into dialysis.

The RHA reiterates its strong opposition to the use of dialysis treatment duration as the basis of ESRD PPS reimbursements. This method is an inaccurate and inappropriate method for determining the appropriate level of dialysis treatment and if implemented, could exacerbate health disparities and negative outcomes for beneficiaries. While many patients achieve optimal health outcomes through receipt of thrice-weekly dialysis for roughly three to five hours per session, patients with chronic pain, complex co-morbidities, or other physical limitations may require shorter, more frequent dialysis treatment sessions. Furthermore, while non-compliant patients may benefit clinically from longer dialysis treatment times, they may refuse to remain on dialysis for longer duration periods for reasons largely outside of a facility's control. Lastly, using dialysis treatment duration to differentiate treatment cost variability amongst ESRD patients could incentivize some providers to abuse the system by increasing dialysis treatment times beyond periods that are medically necessary or keeping patients on the cheapest dialyzer for the full five hours of treatment. These outcomes are neither good for ESRD patients nor the Medicare program and are not based on the sound medical standards of practice, rendering the dialysis treatment duration an ineffective metric on which to base the ESRD PPS payment system. **RHA requests that CMS make refinements to the existing ESRD PPS structure based on**

[33] Johns Hopkins University, 2020, https://publichealth.jhu.edu/2020/the-racial-inequities-of-kidney-disease

patient-level characteristics and facility-level factors that more accurately differentiate the costs of treatment for individual patients with unique care needs.

Finally, the RHA appreciates the opportunity to reiterate our previous recommendations to CMS to remove the current comorbidity adjustments from the ESRD PPS and replace them with adjustments that align with the care of high-complexity, high-cost patients. In CY 2016, CMS removed two comorbidity adjustments (bacterial pneumonia and monoclonal gammopathy) used at the time because 1) patients had to undergo undue burden for clinical testing to meet CMS' documentation requirements and 2) the diagnoses were poorly identified on dialysis claims. The RHA agrees with MedPAC[10] and others that CMS should remove the remaining four comorbid payment adjustments from the ESRD PPS for similar reasons. The current comorbidity adjustment factors do not align with the particularly high-cost, high-complexity patients and can also be very burdensome to obtain. Anecdotal evidence from a literature review and Technical Expert Panel convened in May 2020 by Dobson DaVanzo on behalf of RHA generally confirmed MedPAC's findings, indicating that ESRD PPS comorbidity adjustors are difficult to document and therefore comorbidity payment adjustments are rarely made, especially to freestanding facilities.

We recommend that CMS evaluate a number of comorbidities or subpopulations to identify characteristics of the high-complexity, high-cost patients suggested above. We recommend however that CMS do not limit their analysis to only costs to Medicare (via reimbursement) but also costs to the dialysis facilities to help provide high quality care. Non-ambulatory persons are another patient population whose complex needs are not adequately accounted for in the ESRD PPS. When a non-ambulatory patient arrives for dialysis care, the dialysis staff will often provide hands-on assistance to the patient, helping them into the building and safely to their station. All the while, that staff person is unable to care for other patients. A host of other social risk factors can significantly impact the delivery of care and associated health outcomes for Medicare beneficiaries with ESRD. For many communities, pervasive structural and social barriers prevent access to needed health care and social services, translating into sicker patients requiring higher resource utilization and costlier overall care.

The RHA would recommend evaluating the following factors, and combinations of these social factors, as part of CMS' re-evaluation patient and facility costs associated with their ESRD treatment:

- insurance status;
- behavioral health conditions;
- ventilator use;
- pre-transplantation preparation;
- education level;
- lack of adequate primary care access (especially pre-dialysis);
- amputation or otherwise non-ambulatory;
- wound care needs;
- non-compliant dialysis patients;
- housing insecurity;
- limited English proficiency;
- food insecurity;
- transportation insecurity; and
- weak or lack of social network support.

Another subpopulation with significant disparities are undocumented immigrants with ESRD who face severely limited options for dialysis care. While we understand that this is outside the scope of the ESRD

PPS, there are substantial equity concerns and also impacts on the dialysis provider community as a result of this issue. They are not eligible for Medicare or assistance through the Affordable Care Act (ACA) marketplaces, and a majority cannot afford private insurance. Only 12 states classify ESRD as an emergency medical condition under Medicaid. For those residing in the 38 remaining states, intermittent emergency-only dialysis to treat life-threatening manifestations of ESRD is the only treatment option available.[34] Recognizing their need for life-saving treatment and in an attempt to reduce the number of costly emergency room visits, dialysis units often end up accepting and caring for these patients, thereby incurring the associated costswith no secure source of reimbursement . In recent years, RHA members have seen an uptick in the provision of care for this patient population, the financial impact of which is becoming increasingly unsustainable. To reduce the financial burden shouldered by dialysis facilities and expand equitable access to life-saving dialysis care, RHA recommends that CMS should issue guidance to states to encourage expansion of Emergency Medicaid to undocumented people with kidney failure in all states that do not currently do so.

The following section is responsive to these questions in the RFI:

- *What are the challenges, and suggested ways to address, defining and collecting accurate and standardized, self-identified demographic information (including information on race and ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, and language preference) for the purposes of reporting, stratifying data by population, and other data collection efforts that would refine ESRD PPS payment policy.*
    a. *What impact do social determinants of health (SDOHs) have on resource use and treatment costs for patients who are medically underserved?*
    b. *Which SDOHs should data collection include?*
    c. *How should data regarding SDOH be collected?*
- *How can CMS better use existing data sources to identify unmet needs among specific subpopulations?*

Please see our response to the earlier questions in this RFI on the impact of SDOH have on resource use as well as the SDOH categories that would be most critical to track over time.

The challenge of defining and collecting an accurate, standardized set of demographic and social needs information is not one faced solely by dialysis providers. The RHA recognizes that CMS is evaluating various options for the collection of this information in ways that are accurate but do not increase reporting burden on already very taxed healthcare personnel. The RHA makes three specific suggestions about use of existing data sources to identify unmet social needs:

1) The RHA recommends that CMS collect data regarding SDOH risk factors using Z codes, so that the agency can monitor, research, and implement interventions specific to populations experiencing SDOH barriers over time. Unfortunately, as of 2019, only 1.59 percent of Medicare FFS beneficiaries had claims with Z codes included[35]. To encourage broader adoption of these codes, the RHA suggests financially incentivizing the use of Z codes within Medicare FFS.
2) In addition, RHA recommends collecting demographic and social needs information including making more extensive use of the SDOH factors included on the on the 2728 ESRD Medical Evidence Report Form. The 2728 form is completed at dialysis initiation and includes

[34] Nguyen OK, Vazquez MA, Charles L, et al. Association of Scheduled vs Emergency-Only Dialysis With Health Outcomes and Costs in Undocumented Immigrants With End-stage Renal Disease. JAMA Intern Med. 2019;179(2):175–183. doi:10.1001/jamainternmed.2018.5866

[35] CMS Office of Minority Health, 2019, https://www.cms.gov/files/document/z-codes-data-highlight.pdf

information about the patient's current social needs. This report would require updates over time to gain a more up-to-date picture of a patient's social needs. While there would be some burden associated with this proposal, it would be leveraging data and processes that are already in use within dialysis facilities.

3) Lastly, most of the demographic and social determinants of health information is tracked electronically by dialysis facilities in their electronic medical record (EMR). CMS should work with dialysis facilities and EMR vendors to explore the possibility of collecting this information electronically, without requiring manual data extraction or uploading from dialysis facility personnel.

Pediatric Patient Population

The following section is responsive to these questions in the RFI:

- *How could refinements to the ESRD PPS payment policy mitigate health disparities in the pediatric population?*
- *Should a pediatric dialysis payment include a specific payment modifier on the claim so that costs for providing pediatric dialysis can be further delineated with alternative payment sub-options?*
- *Are there specific comorbidities that should be examined when calculating the case-mix adjuster?*
- *Are there other direct patient care labor categories that should be considered when determining the cost to provide renal dialysis services to pediatric patients, and if so, which ones?*
- *How should CMS revise case-mix categories in the ESRD PPS to better represent the pediatric population?*
- *Are there SDOH that are specific to the pediatric ESRD population?*

The RHA appreciates that CMS is acknowledging the needs of the pediatric dialysis patient population. Pediatric patients have unique care needs that typically require a much higher overall intensity of labor-related services. As CMS notes in the proposed rule, roughly double the person-hours are contributed toward a pediatric dialysis treatment compared to an adult dialysis treatment, and pediatric treatment services require unique staffing and supply needs. In alignment with the TEP recommendations, the RHA contends that current payments do not accurately reflect the true costs of treating pediatric patients and that as such, this patient population merits separate formal consideration in the ESRD payment system.

Moreover, CMS should introduce a third age category (newborn to age 3) to the pediatric patient-level adjusters and provide a separate payment to dialysis providers caring for this complex and highly vulnerable pediatric patient population. These young children require one-on-one staffing during their dialysis sessions due to their age, but these children also require additional specialist and psychosocial supports.

Pediatric patients also experience unique comorbidities beyond those included in ESRD PPS case-mix adjustment. When calculating the patient level case-mix adjuster, CMS should consider conditions such as cardiac disease, seizure disorders, congenital abnormalities, cardiac malfunction, as well as the numerous lung diseases that are frequently seen among infants born prematurely. Beyond these physical conditions, pediatric patients often experience severe psychological challenges as they navigate their disease management, as do their parents and caregivers, all of which should be considered in case-mix adjustment.

Because pediatric patients require a more specialized set of payment adjustments than used currently in the ESRD PPS, the RHA supports the inclusion of a specific payment adjustment on pediatric dialysis payment claims. Specifically:

Overhead costs: Overhead costs can represent approximately half of total costs incurred by outpatient hospital-based pediatric dialysis units, including: governance, amortization, building depreciation, insurance (liability and employee), legal fees, administrative staff, utilizes, documentation, billing, supplies (need to stock a variety of disposable supplies to accommodate differently-sized patients with limited purchasing power due to lower patient populations compared to adult facilities), and equipment (certain specialty equipment such as equipment for blood volume monitoring is required in patients weighing less than 35kg).

Psychosocial supports: Outpatient hospital-based pediatric dialysis units offer psychosocial supports unique to pediatric care, which can include: financial support for families of pediatric patients to cover the ongoing substantial costs of care; case management for each aspect of the child's health – including, but not limited to, ESRD; child life specialists; creative arts therapists; psychologists; school liaisons; pediatric dietitians (with frequent evaluation to assess and promote caloric intake and growth); and camping and other social experiences (often funded through external sources).

Nursing personnel: Outpatient hospital-based pediatric dialysis units uniquely bear partial salary costs due to a dependency upon skilled care expressed in a higher nurse-to-patient ratio with more registered nurses than technicians. For example, with respect to the to the State of Texas dialysis technicians are prohibited from caring for patients weighing less than 35kg.

Clinician personnel: Outpatient hospital-based pediatric dialysis units support highly skilled pediatric nephrologists and pediatric nephology nurse practitioners. Notably, unlike adult nephrologists, pediatric nephrologists visit the patient each time the child receives a treatment. Pediatric outpatient dialysis units also uniquely require supportive care help for patients undergoing pediatric surgeries, vascular surgeries, and pediatric anesthesia.

Specialized pharmacy needs: Outpatient hospital-based pediatric dialysis units have unique pharmacy needs not covered by Medicare, including electrolytes supplements and others.

Home dialysis: Home dialysis is the primary modality for pediatric patients. The current Medicare payment system does not adequately cover the equipment, supplies, training, and nursing costs necessary for pediatric home dialysis.

3. Quality Indicators for Home Dialysis Patients:

We appreciate CMS' interest in monitoring the quality of care for home dialysis patients, a population that is not adequately being captured by the ESRD QIP. In addition to our comments on home dialysis below, please see recommendations within the ESRD PPS portion of this comment letter as well as in the Health Equity Issues RFI response above. Our response addresses the following question in the RFI:

- *Strategies to monitor and assess the quality of care delivered to patients who receive dialysis at home.*

The RHA agrees that monitoring the quality of care of patients receiving dialysis at home is critically important – especially with the significant financial incentives that certain dialysis providers face under the ETC model. While some measures in the QIP do apply to home dialysis patients, we agree with CMS that the QIP does not adequately apply to facilities that have high rates of home dialysis. We understand from some of our RHA members that some home-only programs are disadvantaged greatly by QIP

scoring, despite pursuing a policy priority of CMS to encourage additional adoption of home modalities. **As such, we strongly recommend that CMS revise the QIP methodology for home dialysis programs, to reweight measures, establish appropriate benchmarks, and create reporting minimums for the home dialysis programs.**

There are many ways that the quality of care could be monitored and assessed for patients who receive dialysis at home, whether it be through monthly face-to-face visits with dialysis facility practitioners, via patient surveys, or through technology resources, among others. It should be noted, however, that the ESRD QIP is not the only opportunity for quality improvement and monitoring within dialysis facilities. The ESRD Networks, for example, are tasked with driving significant improvement in home dialysis rates so could certainly have a focus on monitoring the quality of care delivered to home dialysis patients. So, while our response addresses opportunities to monitor the quality of care for home dialysis patients – something we wholeheartedly agree with – **we do not agree with including additional measures within the ESRD QIP.**

Despite this, however, if CMS were to finalize inclusion of home dialysis patients in the QIP, RHA strongly recommends that all measures be considered reporting only, and that any patients that reside in a nursing home be excluded from the definition of "home" as their care needs are substantially different than a typical home dialysis patient.

One avenue to explore for monitoring home dialysis care is via technology. As the RHA has noted in previous comment letters, remote patient monitoring (RPM) has been shown to reduce hospitalizations in the home dialysis population and provides physicians with patient dialysis information in real-time, allowing for efficient monitoring of treatment delivery and timely adjustments in patient care between in-person visits.[36] Telehealth and RPM can additionally play an important role in addressing the current shortage of dialysis nurses and ensuring that patients maintain high quality care while dialyzing at home. These digital health technologies lead to fewer in-person visits and travel time saved, reducing the cost of care delivery and enabling nurses to take on more home dialysis patients. During this time of unprecedented staffing shortages, increasing access to telehealth and RPM is an effective, responsible way to ensure patients can safely continue high-quality home dialysis services. RHA continues to advocate that telehealth visits become a permanent part of the Medicare program and to create coverage and reimbursement policies that promote remote monitoring between in-person appointments.

The following response addresses this question in the RFI:

- *Ways to support more equitable access to home dialysis across different ESRD patient populations.*

A multitude of barriers stand between patients and their ability to make an informed decision on dialysis modality. Many patients lack an understanding of treatment options, cannot afford the high costs associated with dialyzing at home, and are restricted by SDOH challenges like lacking caregiver support, inadequate space for home dialysis equipment and supplies, and unreliable access to the transportation, nutrition, and home environment needed to sustain home dialysis. Patient access to dialysis modality choice is further limited by the number of facilities providing home dialysis optionality. Dialysis centers seeking to develop and sustain home dialysis programs face prohibitive equipment and supply costs, inadequate reimbursement by the ESRD PPS, and unprecedented shortages in their healthcare workforce.

[36] Peritoneal Dialysis International, 2019, https://journals.sagepub.com/doi/10.3747/pdi.2018.00287

Patients from low-income and minority communities tend to have lower levels of health literacy and often face cross-cultural communication challenges and language barriers in healthcare settings. To ensure dialysis modality choice is equally accessible to all patients, kidney care teams must provide all patients with easy-to-understand educational materials on disease progression and treatment options, with information disseminated in the patient's native language and/or with the assistance of a healthcare interpreter or translator.

The timing of this education is also incredibly important. Teaching patients with advanced chronic kidney disease about the upcoming signs of kidney failure and dialysis treatment modalities can slow the disease's progression and help reduce the risk of "crashing" into dialysis. RHA recommends establishing standard requirements for all kidney care providers to talk with patients about dialysis modality options early on, and prior to starting dialysis whenever possible. This will allow patients more time to absorb information, ask questions, and make informed decisions on the treatment modality that makes the most sense for them. As noted previously, RHA supports expanding the existing KDE benefit whereby more patients can learn about kidney disease management and dialysis modality options.

Beyond education, to support equitable access to home dialysis, patients must have access to a number of supports at home. Many patients require the assistance of a trained caregiver to administer the dialysis, including maintaining and cleaning the dialysis equipment. Patient homes must also have sufficient room to accommodate the dialysis machine, access to reliable electricity and internet connection, and source of clean water, depending on the equipment used. Patients who face SDOH concerns, such as a reliable caregiver or supportive housing, would not be good candidates for home dialysis modality unless additional supports could be provided. To broaden equitable access to home dialysis, CMS should offer payment options for the modifications necessary to convert a patient's home into a safe environment for dialysis therapy.

While home dialysis is often viewed as a solution to alleviate transportation challenges associated with in-center care, transportation to home dialysis training also creates a barrier to home dialysis. During the period of home dialysis training, patients are required to make frequent trips to training locations which are not always located in their nearest dialysis facility (which could still require significant travel time). For patients living in underserved or rural areas without reliable transportation, home dialysis training may be inaccessible. The RHA recommends that telehealth be used to the greatest extent possible and training in the home be offered for patients with transportation barriers. CMS should remove financial barriers associated with accessing home dialysis, such as removal or reduction of patients' required copayment for home dialysis training. Lastly, CMS should evaluate opportunities to provide financial support for staff-assisted home dialysis, so that patients who do not have access to a trained caregiver would be able to access the benefits of home dialysis.

4. Request for Information on Potential Future Inclusion of Two Social Drivers of Health Measures

RHA members provide care to some of Medicare's most vulnerable patients, and we share in CMS' commitment to continually refine ESRD facilities' healthcare delivery practices to reduce health disparities and build equity. Screening for health-related social needs is one important step in recognizing disparities and improving health outcomes for underserved communities. **The RHA fully supports the intent of the two social drivers of health measures proposed to encourage screening and follow-up for any identified social needs but does not recommend the addition of these measures in the QIP.** For reference the proposed measures are below:

- *Screening for Social Drivers of Health (which would assess the proportion of a facility's patients that are screened for one or more social drivers of health in the five core domains, including food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety)*
- *Screen Positive Rate for Social Drivers of Health (which would assess the proportion of patients who screen positive for health-related social needs in five core domains)*

Dialysis facilities take seriously their duty to help address patient needs, whether medical, social, or behavioral. In accordance with ESRD Conditions for Coverage requirements at 42 C.F.R. 494.90, facilities must "develop and implement an individualized comprehensive plan of care that specifies the services necessary to address the patient's needs, as identified by the comprehensive assessment and changes in the patient's condition." Among other things, the comprehensive plan of care must assess patient psychosocial status. Specifically, the dialysis facility's interdisciplinary team, which includes social workers, must provide the necessary "counseling services and referrals for other social services, to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis."[37] To meet the requirement to fully assess and then address the entire spectrum of patient needs, dialysis facilities are already conducting SDOH screenings and working to close needed care gaps, the results of which are incorporated into a patient's comprehensive plan of care.

Moreover, many dialysis facilities also administer the Kidney Disease Quality of Life (KDQOL) survey and submit data as part of the Dialysis Outcomes and Practice Patterns Study (DOPPS). The KDQOL survey collects data annually for each patient on their burden of illness, social interaction, staff encouragement, and patient satisfaction, with the overall goal to monitor the impact of dialysis on patients' perceptions of their own physical and mental function.[38] While not the same as a SDOH screening assessment, the KDQOL provides important insights into the patient's needs and challenges that can then be addressed by the facility. The DOPPS collects hemodialysis, peritoneal dialysis, chronic kidney disease treatment, and dialysis practice patterns on a representative sample of patients across the country. Patient demographics are one of the data elements in the DOPPS that have been collected consistently since 1996.[39]

RHA fully acknowledges the value of these proposed Social Drivers of Health measures to track the incidence of social needs in this population and encourage quality improvement activities over time. However, we are concerned with the reporting burden on providers, particularly as facilities continue to face critical staffing shortages. Given the existing reporting and screening requirements that require dialysis facilities to effectively screen for and address social drivers of health, RHA members do not recommend the addition of any Screening for Social Drivers of Health measures for reporting by dialysis facilities. Furthermore, the RHA questions whether these measures are appropriate for the QIP, which bases a facility's payment based on its differential performance under the measure. In particular, we caution CMS in its proposal of the second measure, which requires reporting of positive screenings. This measure may disproportionately affect dialysis facilities, such as those who are members of the RHA, who are caring for a disproportionately vulnerable patient population. Modifying dialysis payment through the QIP based on the rate of positive social needs will result in *fewer* resources for facilities with

[37] ESRD Conditions for Coverage requirements at 42 C.F.R. 494.90 (Interpretive Guidance tag V552) https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter09-01.pdf

[38] About KDQOL Complete — KDQOL Complete, https://www.kdqol-complete.org/about/kdqol

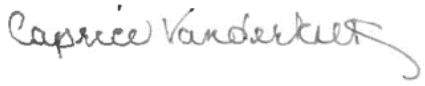
[39] https://www.dopps.org/PartnerwithUs.aspx

higher social needs, the exact opposite of what RHA is advocating elsewhere in our comments. As such, we recommend that CMS explore other opportunities to leverage already collected SDOH data sources to help ensure that a patient's needs are understood and addressed appropriately, instead of introducing new measures and processes that create additional burden on dialysis providers.

Closing

In conclusion, the RHA again wishes to thank you for the opportunity to comment on CMS-1768-P. We believe that the recommendations outlined above will enable CMS to more accurately account for the long-term impact of the COVID-19 pandemic on provider costs as part of the ESRD PPS, expand equitable access to care for low-income and underserved patients, and ensure that dialysis facilities can continue to deliver high-quality dialysis treatment to patients under the ETC model. We look forward to working with CMS to clarify and improve these proposals prior to the finalization of the CY 2023 ESRD PPS. If you have any questions concerning our comments, please do not hesitate to call RHA Executive Director Marc Chow at (215) 564-3484.

Sincerely,



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RHA President