August 26, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-1749-P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

Dear Administrator Brooks-LaSure,

On behalf of the more than 30 organizations working together to advance kidney care through Kidney Care Partners (KCP), I want to thank you for the opportunity to provide comments on the "End-Stage Renal Disease [ESRD] Prospective Payment System [PPS], Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury [AKI], End-Stage Renal Disease Quality Incentive Program [QIP], and End-Stage Renal Disease Treatment Choices [ETC] Model Proposed Rule" (Proposed Rule). This letter focuses on the ESRD CY 2022 ESRD PPS and AKI policies, as well as the request for information related to that rule. Our comments on the ESRD QIP and ETC Model will be provided in separate letters.

KCP is an alliance of more than 30 members of the kidney care community, including patient advocates, health care professionals, providers, and manufacturers organized to advance policies that support the provision of high-quality care for individuals with chronic kidney disease (CKD), including those living with End-Stage Renal Disease (ESRD).

KCP wants to thank CMS for working with KCP members during the pandemic. As the Centers for Disease Control and Prevention (CDC) has recognized, patients with Chronic Kidney Disease (CKD), especially those with Stage 5 kidney failure, are at a heighten risk of contracting COVID-19. Thus, finding ways to promote care in the home through expanding telehealth services and access to laboratory testing in the home are important steps to reduce the risk of infection. In addition, allowing facilities to have the flexibility to implement programs to help patients who require in-center hemodialysis, even after diagnosed with COVID-19, has helped to ensure that all patients receive the care they need during these difficult times. Most importantly, we appreciate the Biden-Harris Administration's decision to allocate vaccines directly to dialysis facilities to allow them to leverage their thrice weekly contact with patients and encourage them to be vaccinated.

In addition, we strongly support the Administration's efforts to address inequities in health care. As we described in detail in our July letter to the Office of Management and Budget (OMB) request for information "Methods and Leading Practices for Advancing Equity and Support for Underserved Communities Through Government," patients with kidney disease are disproportionately from communities of color and experience inequities in the delivery of health care. Throughout this letter, KCP makes recommendations that we believe will help address this systemic problem.

However, the modifications to the ESRD PPS and QIP alone are not enough. The systemic barriers to accessing basic health care likely play a substantial role in these individuals developing kidney disease and progressing to kidney failure. The leading causes of CKD and ERSD are hypertension, diabetes, and obesity. Black and Hispanic individuals are diagnosed with these diseases more than other Americans.[1] We know from several years of research that people of color have greater difficulties accessing preventive care and chronic disease management services.[2] It is very likely that the challenges these individuals faced when trying to access basic health care services resulted in chronic diseases, such as diabetes, obesity, and heart disease, not being fully managed, which led to the development of kidney disease. KCP renews its commitment to work with CMS and other federal agencies to find ways to address these challenges that exist prior to an individual's kidneys failing.

I. Comments on CY 2022 ESRD PPS

KCP supports several of the updates that CMS proposes for CY 2022. We also recommend modifications to the outlier pool and the use of comorbid case-mix adjusters. While we continue to recommend changes to the age and weight patient-level adjusters, as well as to the facility-level rural and low-volume adjusters, we recognize that CMS intends to address these larger reforms in a future rule, so have focused on those comments in the Request for Information section of this letter. However, we believe the recommendations in this section could and should be implemented for CY 2022.

KCP recognizes the end of the phase-in for the wage index adjustment and supports the final phase-in of the wage index. As noted in previous letters, we would like to work with CMS to consider ways to better tailor the wage index for the ESRD program.

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[1] Richard V. Reeves & Faith Smith. "Up Front: Black and Hispanic Americans at Higher Risk of Hypertension, Diabetes, and Obesity: Time to Fix Our Broken Food System." *Brookings.* https://www.brookings.edu/blog/up-front/2020/08/07/black-and-hispanic-americans-at-higher-risk-of-hypertension-diabetes-obesity-time-to-fix-our-broken-food-system/ Aug. 7, 2020). accessed June 28, 2021.

[2] Kenneth E. Thorpe, Kathy Ko Chin, Yarira Cruz, *et al.* "The United States Can Reduce Socioeconomic Disparities by Focusing on Chronic Diseases." *Health Affairs* (Aug. 17, 2017) https://www.healthaffairs.org/do/10.1377/hblog20170817.061561/full/. accessed June 20, 2021.

KCP also supports the updated calculation to the base rate. We recognize that CMS does not have the authority to eliminate the productivity factor adjustment from this calculation, but reiterate our concern that the overall negative Medicare margins (which remain low even when the temporary TDAPA amounts are removed for the margin analysis) and the experience of dialysis facilities argues against the idea that productivity can be improved year-over-year.

A. KCP support adjusting the Outlier Pool and continues to recommend that CMS address the systemic under-payment created by the current policy.

Since the inception of the ESRD PPS, the outlier pool withhold amount has been a difficult policy to implement. While no one in the kidney community expects a dollar-for-dollar match between the withhold and the amount paid out, there is no question that the outlier amounts paid out have consistently and substantially missed the mark for the past 10 years.

The loss of these dollars to the system is significant. The Moran Company estimates that at least $6.29 per treatment intended for patient care "leaked" out of the bundle due to sequestration, the QIP cuts, and the outlier pool shortfall. Given changes in the data set, The Moran Company has not been able to draw a clear comparison for the "leakage" for adjusters, but historically those loss were also significant. These are dollars that were supposed to go to patient care and education, but have been lost to the system. Given the disproportionate impact of kidney disease on Black and Hispanic individuals, the outlier pool is perpetuating an inequity in the funding of health care services for these marginalized individuals that could be easily addressed.

We appreciate that CMS has recognized that nearly each year the outlier pool has failed to pay out at the predicted 1.0 percent level. There has only been one year out of the last 10 when the outlier pool has even come close to meeting that level. As we have noted in previous letters, the statute does not mandate that the outlier pool withhold 1.0 percent. We again encourage CMS to align it with the actual amount being paid out. In this case, because the CY 2020 claims data showed that outlier policies represented 0.6 percent of total payments,[3] Given this data point, CMS could set the CY 2022 outlier pool at 0.6 percent. While we understand the proposals to change the FDL and MAP amounts, these efforts have not worked to right-size the outlier pool in the past. The fact that the problem has been consistent during the last 10 years suggests a different solution is necessary to address the problem.

Addition, KCP is concerned that the withheld dollars are not returned to the system to go to patient treatment and education. Any year when the outlier pool retains dollars

[3]Display Copy of Proposed Rule page 24.

that are not paid out, KCP recommends that CMS reallocate those dollars to support reducing the barriers that create inequities in the care dialysis patients receive. These funds could be used to support educational programs, support pilot programs related to improving specific health care outcomes (such as nutrition), or simply returned to the system as an increase in the base rate. We appreciate that some of these ideas may need to be addressed with legislation, but we also believe that it is important to consider creative solutions to this long-standing problem that can help those patients most in need.

Additionally, with the advent of new products entering the ESRD bundle and qualifying for outlier payments, there may be a shift of the patients who qualify for outlier payments. It is also important to address this emerging issue to protect access to the current services that qualify for outlier payments, as well as the innovative products. The Moran Company has found that the cases qualifying for outlier payment could shift dramatically. The proportion of the outlier payments associated with patients receiving any new drug are likely to increase. Based its analysis of the inclusion of the first new drugs into the bundle, The Moran Company found that many patients whose treatments historically qualified for outlier payments would no longer qualify under the current policy due to the significant increase in the outlier threshold. Any new product that qualifies for the outlier pool and has a significant cost associated with it will lead to higher threshold amounts. This result will make it more difficult for the outlier pool to support the costs associated with other products, because those costs alone may no longer meet the higher threshold. This situation could lead to the outlier pool being primarily consumed by a single group of services.

There are likely different ways to address this issue as new products enter the bundle. KCP would like to work with CMS on developing a long-term solution to ensure outlier availability to mitigate losses incurred by facilities that treat patients with higher-than-average costs and to apply the outlier payments to a variety of high-cost patients. For a more detailed discussion, please refer to Section IV.B. below.

B. KCP encourages CMS to eliminate the remaining comorbid case-mix adjusters.

KCP appreciates the preamble discussion noting that CMS will consider revisions to the ESRD PPS in the next rulemaking cycle, including re-examining the patient- and facility-level adjusters. We have provided responses to the Request for Information in Section III of this letter reiterating our requests to revise the age, weight, rural, and low-volume payment adjustment adjusters. However, we believe that CMS could address the problem of the comorbid case-mix adjusters for CY 2022, as it did when it removed bacterial pneumonia and monoclonal gammopathy for CY 2015. As MedPAC and The Moran Company analyses show, facilities are not claiming these adjusters. Additionally, there has been no evidence that patients with any of these comorbid conditions have difficulty accessing care. The comorbid case-mix adjusters are patient characteristics for which CMS has the discretionary authority to establish; the statute does not mandate their creation or

application.[4] Given that these adjusters are not being paid out as expected, do not target higher cost patients, and are difficult to document, KCP asks that CMS remove these adjusters for CY 2022 and not delay that action until a future rulemaking cycle.

It is important to remove these adjusters because the money withheld to fund them is not being paid out in claims. In 2015, MedPAC compared reporting of the comorbidities on 2013 dialysis facility claims with the prevalence of the comorbidity reporting on the physician (carrier) and inpatient and outpatient hospital claims. MedPAC found that individuals with these comorbidities were identified on dialysis facility claims only a fraction of the time the comorbidities for the patients were reported on the physician, inpatient, and outpatient hospital claims:

- 19 percent of the time for pericarditis;
- 25 percent of the time for gastrointestinal tract bleeding with hemorrhage;
- 47 percent of the time for hereditary hemolytic/sickle cell anemias; and
- 36 percent of the time for myelodysplastic syndrome.[5]

Using 2019 data, The Moran Company found that between a small percent of the adjusters are claimed. Specifically, it found the following percentages for each of the current comorbidity adjusters were claimed:

- 9 percent of the time for pericarditis;
- 10 percent of the time for gastrointestinal tract bleeding with hemorrhage;
- 43 percent of the time for hereditary hemolytic/sickle cell anemias; and
- 16 percent of the time for myelodysplastic syndrome.

All of the comorbidity adjusters were claimed less frequently than they were in 2013.

The money not claimed is not returned to the system and cannot be redirected to patients who would otherwise benefit from the dollars being spent specifically on patient care. This means that the dollars the Congress intended to go to providing items and services for individuals who receive dialysis are being inappropriately diverted away from that care. If the adjusters were not included for CY 2022, the base rate would increase by the amount currently being withheld. As MedPAC also noted, to the extent these adjusters are not claimed, but the patient actually incurred a higher cost, the outlier pool will capture these additional costs.

It is also important to remove these adjusters because they are not necessary to protect access to dialysis services. We appreciate that CMS may have adopted these adjusters initially to address the use of certain separately billed drugs when they were

[4]SSA § 1881(b)(14)(D)(i).
[5]MedPAC. "Letter to Acting Administrator Andrew Slavitt, Centers for Medicare & Medicaid Services." (Aug. 6, 2015).

added to the bundle in 2010. The Agency noted in the CY 2011 final ESRD PPS rule that "[o]ur analysis has identified certain co-morbidity diagnostic categories that have shown higher use of separately billed renal dialysis items and services, which are recognized for a payment adjustment under the ESRD PPS."[6] CMS has stated that "the costs were identified with increased utilization of ESAs and other services."[7] Clinical practice has changed significantly since the data used to establish these comorbid case-mix adjusters were collected and analyzed.

Recent work by CMS contractors during the 2019 and 2020 ESRD PPS Technical Expert Panel (TEP) suggests that there is very little variation in cost incurred to treat dialysis patients with these comorbidities. The adjusted r-squared (approximately .25) for the equation including age, BMI, and BSA, and low volume and rural adjusters, and the four comorbid conditions is quite low, which suggests limited predictive ability, and the extent to which the inclusion of the four comorbid conditions move the adjusted r-squared is not reported. The coefficients for the current comorbidity adjusters provide very little redirection of resources. The contractor has not provided the p-values or confidence intervals for the included terms in these models.

Adjuster	**Refined one-equation (before changes to control variables)**	**Refined one-equation (after changes to control variables)**
Adjusted R-Squared (for all adjusters	0.237	0.267
Pericarditis (acute)	1.028	1.03
Gastro-intestinal tract bleeding (acute)	1.055	1.059
Hereditary hemolytic or sickle cell anemia (chronic)	1.128	1.128
Myelodysplastic syndrome (chronic)	1.06	1.063

Source: Acumen. "Design of the ESRD TEP: Technical Expert Panel." 39 (December 10-11, 2020).

These adjusters were identified when CMS first established the ESRD PPS and ESA were added to the bundle. Much has changed since 2011, including the costs of ESAs. Given these known changes and the clinical consensus that these adjusters are not benefiting patients, KCP asks that CMS eliminate the comorbidity adjusters for PY 2022. The years of discussion and the RFI questions in this rulemaking should constitute

[6] *Id.* at 49100.
[7] CMS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Proposed Rules." 80 *Fed. Reg.* 37808, 37817 (July 1, 2015); *see also* CMS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule and Proposed Rules." 75 *Fed. Reg.* 49030, 49099 (April 12, 2010).

sufficient notice to support their elimination during this rulemaking cycle and not require them to remain in place for yet another year.

When these adjusters remain in effect and are not claimed, dollars meant for patient care are removed from the system. These dollars could be directed to help address patient needs, such as improving patient education about home modalities, helping patients navigate the transplant process, improving the placement of fistulas, receiving adequate dialysis doses (including treatment compliance), and achieving targeted hemoglobin levels. All of these metrics are associated with decreased dialysis survival and which Blacks are less likely to receive.[8]

C. KCP continues to support TPNIES, but urges CMS to remove the offset policy which dilutes the incentive to innovate.

KCP supports a transitional payment adjustment for truly innovative devices that will be added to the ESRD bundle. It is also important that the TPNIES policy be predictable and provide sufficient incentives so that innovators see it as a meaningful and real option that will encourage them to enter a market that historically has not fostered or encouraged innovative technologies.

To that end, we remain concerned with the offset amount being applied to TPNIES. As The Moran Company's analysis from 2020 showed, the offset combined with the 65 percent fraction of the MAC-determined preadjusted treatment amount would undervalue any innovative product that would meet the TPNIES qualifying criteria.

The Moran Company found that with perfect adherence and patient health, the maximum TPNIES amount would be 26 percent of the cost of the device paid over two years. Given that the proposed TPNIES amount is only a portion of the cost providers incur when using the device, it does not make sense to further reduce the TPNIES amount with the offset. Limiting the incentive in such a manner is unlikely to drive the innovation CMS seeks to promote, further limiting it as the offset proposal would only further reduce the likelihood of adoption.

D. KCP continues to support adjusters to incentivize long-term adoption of truly innovative treatment options for patients.

Individuals living with kidney disease, especially kidney failure, have not experienced the same level of medical innovation that others living with conditions like cardiac disease or cancer have been able to access during the last 30 years. The work HHS and CMS have done to remove barriers to adopting innovative products and services for kidney care is an important starting point to incentivize innovation and innovative

[8]Lauren M. Kucirka, Sc.M., Morgan E. Grams, M.D., M.H.S., Justin Lessler, Ph.D.(3), *et al.* "Age and Racial Disparities in Dialysis Survival." JAMA. 2011 August 10; 306(6): 620–626. doi:10.1001/jama.2011.1127.

treatment options. Fostering innovation in kidney care generally is also central to the Administration's goals of reducing inequities in health care.

The TDAPA and TPNIES have been a positive step toward removing the barriers created by the ESRD PPS. Yet, as currently designed, these policies do not address the need for long-term stability because they do not include policies to adjust the base rate, even in an incremental way, when certain new products are added to the bundle. As noted elsewhere in this letter, even if the KCP-recommended changes to the TDAPA and TPNIES were adopted, it is time to modernize the ESRD PPS to support innovative care options, promote patient choice, and eliminate barriers to care coordination.

TDAPA provides a two-year transition payment for certain new products that are renal dialysis services, but currently CMS only allows for adjustment to the bundled rate incrementally when drugs or biologicals not within an existing functional category are added to the PPS bundle. KCP requests that CMS evaluate all drugs and biologicals that receive TDAPA, including those deemed to be within existing function categories, and incrementally adjust the base rate when that rate does not adequately address the cost of adding the product to the bundle. We also ask that CMS return to the original policy that the TDAPA period would be two to three years and reimbursed at ASP+6 percent. This would allow CMS to collect at least two full calendar years of data to determine the utilization before folding the product into the ESRD bundle.

While we understand that there may be challenges to establishing a TPNIES for capital-related asset devices more generally, these challenges should not be allowed to create a barrier to incentivizing the adoption of truly innovative capital-related assets generally. In addition, we recommend that CMS also apply TPNIES for three years to allow it to assess the effect of adding the devices to the PPS bundle and evaluate the base rate to determine if an incremental adjustment would be necessary to support ongoing access to the device. We support structuring TPNIES to help bring innovative products to all kidney care patients.

Adjusting the base rate for truly innovative products is essential to expanding innovation to those living with kidney disease. The statute establishing the payment system anticipated such adjustments,[9] so there is sufficient authority to provide for these incentives.

In addition, we ask that CMS coordinate the policy with the Medicare Advantage (MA) program, so that the additional funding for these products is also incorporated into the reimbursement MA program. We ask CMS to take steps[10] to ensure that there is adequate funding for innovative products in the MA program as well.

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[9] 42 U.S.C. § 1395rr(b)(14).
[10] *See,* 42 C.F.R. §422.109.

II. KCP supports the proposed AKI rate for CY 2021 and asks CMS to share its monitoring program and the results of it with stakeholders.

KCP supports the proposed AKI rate. Caring for AKI patients has become an even more important aspect of kidney care in America during the pandemic. We are pleased that CMS seeks comments on allowing individuals with AKI to select home dialysis and provide more detailed comments on the RFI in Section III.

We continue to support the current methodology, but as we have noted in previous letters, believe that monitoring data could help address questions about whether the assumptions underlying the ESRD PPS are appropriate for individuals living with AKI. From a clinical point of view, there are many aspects of treating AKI patients that may differ from treating ESRD patients. CMS indicated that it would monitor the benefit so that it could adjust the payment model, if needed. It would be helpful to researchers and clinicians to understand what information is being monitored and the results of that monitoring, especially as CMS seeks comments on ways to adjust the payment system.

III. KCP requests CMS change the price proxy for non-ESA drugs and biologicals.

When CMS established the ESRD PPS, it relied upon a series of proxies for the bundle. As new drugs and biologicals enter the bundle, it is important for CMS to update the proxies to use the most appropriate price proxies for determining the base rate and update each year. KCP requests that in this rulemaking cycle CMS replace the current price proxy for non-ESAs that are not over the counter (OTC) vitamins. Specifically, we recommend that CMS use the BLS Series ID: WPS063 Series Title: PPI Commodity Data for Chemicals and Allied Products-Drugs and Pharmaceuticals, seasonally adjusted. It remains unclear why CMS has yet to modify this proxy, but given the innovative products soon to be available, it is important to change the proxy before January 1, 2022.

The current category references "vitamins," in a way that does not appropriately capture the price of drugs that fall within this category. The drugs in this category represent a small portion of the overall cost of providing dialysis services; however, the need for a more accurate and appropriate price proxy for oral and non-ESA drugs should be addressed now. The current category references "vitamins," in a way that does not appropriately capture the price of drugs that fall within this category. Vitamin D analogs in this category, such as doxercalciferol and paricalcitol, are synthesized hormones that suppress PTH without inducing severe hypercalcemia, distinguishing them from OTC vitamins. These products are all unique chemical entities, FDA-approved, available by prescription only, and indicated for the treatment of secondary hyperparathyroidism (SHPT) which contributes to the development of bone disease. Moreover, these prescription drugs are classified by the U.S. Pharmacopeia in the Medicare Model

Guidelines, a classification system that supports drug formulary development by Medicare Part D prescription drug plans, as "Metabolic Bone Disease Agents," not vitamins.

More importantly, there are new drugs in the pipeline currently that, if the payment system does not create disincentives for their continued development, will likely be added to the bundle during the next two to three years. KCP recommends that CMS establish an alternative price proxy for these other drugs that is based on prescription drugs rather than vitamins and that would include fewer OTC drugs.

IV. Comments on Request for Information (RFI) for the ESRD PPS and AKI Policies

In the RFI section of the Proposed Rule, CMS states "in order to provide payment for oral-only renal dialysis service drugs and biologicals under the ESRD PPS beginning January 1, 2025,…[the agency] will need to propose refinements to the payment system through notice-and-comment rulemaking." Oral-only drugs that are furnished for the treatment of ESRD have yet to be added because either CMS delayed their inclusion or the Congress passed legislation delaying their inclusion. These delays indicate that there are concerns with adding these products to the bundle. KCP believes that these concerns continue to exist and because of them, we ask that CMS exercise its existing authority to further delay the inclusion of oral-only drugs that are furnished for the treatment of ESRD or permanently exclude them from the bundle.

Further delay or permanent exclusion of these products will benefit beneficiaries who require these drugs, relieve burden on providers, and benefit the Medicare program.

Delaying or permanently excluding oral-only drugs in the bundle will be better for dialysis beneficiaries. The Congress created the Part D program to help Medicare beneficiaries better manage their medications and to identify the lowest cost options for their oral medications. When these medications are shifted out of Part D, beneficiaries no longer have access to the advantages of the Part D program, such as medication therapy management programs, drug utilization review, and geographic access standards. In addition, they may experience higher costs because they no longer can "shop around" the large number of Part D plans to select the one that is the best fit for them.

As CMS is aware, the majority of Medicare beneficiaries with ESRD qualify for the low-income subsidy (60.5 percent).[11] An estimated 90 percent of these beneficiaries are eligible for a full premium subsidy. Among these beneficiaries, the majority owe either no co-payment or a low co-payment.[12] For example, for non-institutionalized full subsidy -

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[11] United States Renal Data System (USRDS). *2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States*. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020, https://adr.usrds.org/2020/end-stage-renal-disease/10-prescription-drug-coverage-in-patients-with-esrd.

[12] *Id.*

full-benefit dual eligible individuals with incomes no greater than 100 percent of the federal poverty limit, maximum co-payments up to the out-of-pocket threshold under the standard benefit design are $1.35 for generic and multi-source drugs and $4.00 for other drugs in 2022.[13] The maximum co-payment above the out-of-pocket threshold is $0.[14] The Part D costs can be less than the Part B cost sharing obligations for some beneficiaries.

Delaying or permanently excluding oral-only drugs in the bundle will be better for providers. Current CMS policies create inappropriate burdens on providers. For example, while KCP has requested in previous letters that CMS align the documentation requirements for oral medications to require the "amount dispensed" be used as it is for skilled nursing facilities, CMS continues to require facilities to provide the "amount consumed," which is extremely difficult to assess when patients take oral medications at home. Furthermore, providers have little control over patient adherence to medications that they do not administer during the dialysis treatment itself.

Delaying or permanently excluding oral-only drugs in the bundle will be better for the Medicare program. Permitting these therapies to remain in Part D will alleviate the pressure on the bundle as it is stretched to cover new and innovative treatments for which CMS possesses no flexibility to provide an exclusion. It will also enable CMS to focus more intensely on the bundle as it applies to items and services used in the course of furnishing renal dialysis, as opposed to those utilized by beneficiaries outside of the dialysis facility. In addition, CMS will be alleviated from the need to undertake complex regulatory processes and changes in the coming years to transition these drugs into the bundle; those losing oral-only status will continue to proceed through the transition processes that are already established.

The MA program continues to struggle with adequately incorporating new products, even during the TDAPA period, into their plans. The experience with calcimimetics is an example of the concern. Further delay in adding oral-only products would alleviate the disruptions these changes would create for MA plans with regard to their long-standing contracts with providers.

If CMS does plan on moving forward with adding oral-only products to the ESRD bundle, KCP requests that CMS establish a TDAPA period that will allow CMS to collect the price and utilization data necessary to assess how the bundle payment rate will be adjusted when they are added. With calcimimetics, CMS recognized that it had not included the cost for the drugs in the ESRD PPS base rate when it created the bundled rate. The same is true for phosphate binders (including phosphate lowering drugs), the other oral-only drug class that was referenced in the Congressional delays of their inclusion in the bundle.

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[13] CMS, Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Jan. 15, 2021), https://www.cms.gov/files/document/2022-announcement.pdf.
[14] *Id.*

Therefore, we ask that CMS allow for a 2- to 3-year TDAPA transition period during which time it can assess the cost of phosphate binders and their utilization to adjust the base rate appropriately, before this oral-only class is added to the bundle. A TDAPA period is particularly important for this drug class because more than 90 percent of dialysis patients are prescribed phosphate binders, yet they cannot be administered during dialysis treatment. Rather, they must be taken orally multiple times a day and often with meals and snacks to bind with the dietary phosphorus consumed in food, which is then excreted.

CMS will not be able to appropriately adjust the base rate payment to account for phosphate binder costs without a TDAPA period. Although notation of a prescription for a phosphate binder may be included in a patient's medical record, dialysis facilities do not know whether that prescription is filled through a Part D plan or other creditable drug coverage source, or if the beneficiary has taken the medication.

In addition, CMS does not have adequate data from the Part D program in order to accurately calculate the costs that would be incurred by dialysis facilities if they were to take financial responsibility for the treatment of hyperphosphatemia, a prevalent and serious co-morbidity of kidney disease associated with cardiovascular events, vascular calcification, and death.

As KCP has articulated in the past, Part D data is incomplete. The Part D benefit is voluntary, administered by competitive commercial plans, paid by separate and varying premiums, and has varying coinsurance structures and unique coverage phases. There are contributions from premiums, state Medicaid programs, manufacturers, and negotiated discounts. Costs change during phases of the benefit from deductibles through the coverage gap (or "donut hole") and into catastrophic coverage. Furthermore, not all dialysis patients are enrolled in Part D, and therefore, it is not an adequate data source which CMS could use to accurately value a base rate adjustment on a per treatment basis. Finally, there would be no ability to extrapolate an average cost for each drug, nor make assumptions about the mix or use of therapy options if the clinical and financial responsibility for the disease and its treatment were shifted to facilities.

To ensure adequate payment for the phosphate binder class, a full TDAPA period should be provided during which dialysis facilities can test the efficacy and safety of alternative treatments within their patient population, develop clinical protocols, train staff, negotiate contracts with manufacturers, and establish distribution or dispensing systems. This period would also allow CMS to collect the pricing and utilization data necessary to make the adjustment to the ESRD PPS base rate that reflects the additional costs of the products when bundled.

A. KCP continues to support the elimination of the rural adjuster and the expansion of low-volume payment adjuster (LVPA) that incorporates the dollars allocated to the LVPA and the current rural adjuster.

KCP remains concerned that the current LVPA and rural adjusters which do not target dollars to the facilities that need them the most. MedPAC has raised similar concerns over several years of comment letters. We are pleased that CMS is asking for comments on the current facility-level adjusters.

Specifically, KCP supports a single low-volume facility adjuster that would better target payments for facilities providing fewer than 4,000 treatments per year (the current criteria) and expand the adjuster to a second tier of facilities providing between 4,001 and 6,000 treatments per year. This revised low-volume adjuster would take the place of the LVPA and rural adjuster. The new adjuster could be funded by the current dollars allocated to the low volume and rural adjusters. This recommendation is consistent with the MedPAC recommendation.

KCP does not support the use of census tracts to identify geographic areas with low demand that only suggests the need to incentive facilities to remain in these areas to protect beneficiary access to dialysis treatments. As presented by the TEP contractor, this model is complicated and lacks transparency. It also seems likely to perpetuate the concern that basing adjusters on ZIP codes fails to appropriately target providers with actual low-volume. The tiered model considered by MedPAC and supported by KCP has the advantage of being based on actual patient census numbers over a period of time and includes a mechanism to make sure that bad actors do not "game" the system by limiting facility capacity. It is also transparent in that facilities must attest to their populations. These attestations can be easily confirmed using claims data.

Under the MedPAC suggestion, dollars would be targeted specifically to facilities that have a low volume of patients. These facilities must spread administrative and similar fixed costs over a fewer number of patients, which can make it more difficult for them to have the resources to remain open. While it is true that facilities located in rural geographic ZIP codes would no longer access the rural adjuster if their populations exceeded the thresholders, no facilities currently receiving the LVPA would lose access to the adjustment, unless their patient population increased above the threshold. The dollars would be more appropriately targeted to the facilities that need them.

The Moran Company analysis of these adjusters found that the rural and low volume adjusters overlap. The Facility-Level Impact file shows that of the 330 low-volume facilities 168 are rural, so more than 50 percent of facilities that claimed the low volume adjuster are also claiming the rural adjuster.[15] During previous rulemaking cycles, KCP has

[15] *See* ESRD PPS CY 2019 Proposed Rule Facility Level Impact File.

proposed eliminating the rural adjuster – which is not mandated by statute – and modifying the low volume adjuster – which is required by statute. Based on The Moran Company's analysis, facilities with 6,000 or fewer treatments have significant negative margins. The low volume adjuster could be modified to account for these facilities. KCP continues to propose that CMS replace the current adjusters with a two-tiered low-volume adjuster policy, with the current low-volume adjuster being the first tier and the second tier applying to facilities with 4,001-6,000 treatments per year. This modification can be made without having to create a new model.

Thus, KCP supports moving to a two-tiered low-volume adjuster and eliminating the rural adjustment (and reallocating the dollars to the new low-volume adjuster). We do not support the proposal set forth in the ESRD PPS TEP that would rely upon census track information and a complicated allocation formula that lack transparency.

B. KCP continues to support eliminating the comorbid case-mix adjusters and revising the age and weight adjusters.

1. Response to RFI questions

KCP appreciates that CMS seeks comments on the case-mix adjusters. As noted in Section I, data show that the comorbid case-mix are not utilized. In Section 2, we reiterate our recommendations to refine the age and weight (BSA and BMI) adjusters to better capture and designate higher costs patients. We continue to support the onset of dialysis adjuster without recommending modifications. We do not believe that treatment duration is a factor necessary to establish appropriate adjusters for this population.

The focus of collecting time on machine to determine patient level variation is misplaced. The TEP panelists and observers were virtually unanimous in their comments that pursuing these data elements would not identify high-cost patients and what little variation might be identified would not be worth the burden of collecting the information. The TEP's contractor analysis included data on the average treatment duration for current case-mix adjusters and showed the results for the current adjusters clustered around 220 minutes. The only outlier to this was BSA Category Q5 at 240 minutes.

As TEP panelists and observers argued, these data confirm that there is not significant variation in terms of how much time an individual receiving dialysis spends on the dialyzer. The one exception is related to weight (BSA specifically), which KCP has recommended in previous comment letters be used as a case-mix adjuster. Using BSA as an adjuster is clinically sound as well. Patients who weigh more require more time to dialyze. Simply weighing each patient, which is standard of care today, provides the necessary data to evaluate the appropriateness of this adjuster. The information to claim this adjuster is also straight-forward to obtain and easy to verify. Collecting time on machine data will be burdensome and complex. Some machines may track the time, but others do not. Requiring another obligation on dialysis professional when the outcome is unlikely to

produce a meaningfully better result is not worth the cost and time away from patients. For home dialysis patients who do not have machines that record their time, requiring them to keep treatment logs is also unnecessarily burdensome and intrusive. In addition, dialysis facilities staff based on prescribed time, not on the actual time a patient is on the machine. This approach is the most rationale way to determine staffing levels because dialysis facilities do not have time on machine in advance; they have only the prescribing physician's prescription.

KCP also does not believe that new cost components should be collected on cost reports to infer composite rate costs associated with treatment duration. There is very little variation in the basic composite rate items and services across patients. In addition, cost reports focus on facility-level costs, not patient-level costs, and are not appropriate data sources for collecting data to establish patient-level measures. A cost report-based patient metric offers too much opportunity for noise rather than actual cost difference to be measured. It is a large leap to go from modest correlation (as measured by published R^2) to the causation needed to justify adjusting payments. For the age adjuster specifically, the 2016 run of the ESRD-PPS model showed no variation in separately billable cost among the three major age groupings, which means that the cost report data is entirely responsible for the resulting adjuster.

KCP also finds no advantages to obtaining treatment duration information from blood urea nitrogen time on dialysis through the End Stage Renal Disease Quality Reporting System (EQRS) versus through claims reporting. Because there is no meaningful variation in time on machine other than perhaps when it comes to patients who weigh more, we do not think requiring time on machine to be reported is helpful or necessary to refining the ESRD PPS case-mix adjusters. Using BSA (as described below) is a preferrable approach, and it is already a data point reported on claims.

One of the reasons that KCP remains concerned and sees little value in collecting time on machine is that it will be extremely burdensome to providers and patients. Since the pandemic, dialysis facilities (like many providers across the country) are having a difficult time finding and retaining health care professionals. There are many reasons for this, including several related to caring for vulnerable patients during the COVID-19 pandemic. Adding another paperwork requirement on those professionals who continue to care for patients when that requirement is unlikely to show meaningful variation is difficult to justify. For patients at home, as noted above, it is intrusive to ask them to record their time on machine. It fosters a level of frustration that they have to fill out logs (paper or electronic) and implies a culture of mistrust. It sends the message that the Medicare program (and their providers who must enforce the requirement) do not trust they are following their prescription. Even if Medicare is not paying based on the information or seeking to track patient compliance, the impression is the same. If there were a meaningful benefit from taking this step it could be justified, but experience and the Acumen data tell us that the data will not identify a new and meaningful adjuster(s).

KCP believes that the weight adjusters, particularly BSA, is the most appropriate adjuster and captures any variation that might be linked to time on machine.

The bottom-line is that the community has continually raised concerns about the current adjusters because they do not reflect higher cost patients and do not protect access to care. Collecting time on machine data assumes that there is significant and meaningful variability in this factor that will lead to meaningful changes in the patient-level case-mix adjusters. There is simply no evidence to support this contention. In fact, the existing data support the conclusion that time on machine does not vary significantly expect in terms of BSA, which itself is already an adjuster. There is no need to collect additional data to support what is already known. It is simply not clear what problem would be solved by collecting these data points.

2. KCP recommends modifying the age and weight adjusters.

Age Adjuster. The age adjuster reference group has changed in each of the published runs of the ESRD-PPS model. In the 2011 Proposed Rule the reference (least costly) group was age 45-59. In this run of the model patients age 70-79 were 7 percent more expensive for the delivery of composite rate services than patients aged 45-59. In the second run of the ESRD-PPS model in the 2011 Final Rule the reference group switched to patients aged 60-69. In the following analysis, patients aged 45-59 and 70-79 had virtually identical adjusters, indicating that they were now considered to be approximately the same expense to treat. In the 2016 Proposed Rule, the ESRD-PPS found patients aged 70-79 to be the least costly group. In that analysis, patients aged 45-59 were 6.8 percent more expensive than patients aged 70-79. Taken together, this means that between the 2011 and 2016 analyses of the model, patients aged 45-59 had shifted nearly 15 percent relative to patients aged 70-79. Neither industry experts or MedPAC believe there is a clinical explanation for this substantial change in relative cost. It appears that the age adjuster is picking up statistical noise from some other source, since clinical practice has not changed for these two age groups. CMS should revise the age adjuster so that it is meaningful. We suggest establishing an age adjuster that differentiates between adult and pediatric, consistent with our recommendations on the pediatric adjustments below.

Weight. The current adjusters (BSA and BMI) cancel each other out and fail to achieve the policy goal; therefore, we recommend that CMS adopt the single BSA adjuster. BMI is one of the patient characteristics for which CMS has the discretionary authority to establish an adjuster.[16] KCP supports an adjuster(s) to account for patient weight for the ESRD PPS, but has concerns about the interaction of BMI with the other weight-related adjuster, BSA. In discussing the patient characteristic of weight with the physician, nurse, and other health care professional organizations within KCP, there is a general sense that physicians rely more often on the BSA to adjust patient treatments, because BMI does not take into account a patient's muscle mass. It is also important for evaluating overweight

[16]SSA § 1881(b)(14)(D)(i).

patients, who require more time to dialyze. As currently designed these adjusters cancel each other out for certain patients and do not achieve the goal of addressing higher costs for patients with these characteristics.

BMI and BSA are both variables for the same patient characteristic. As such, they are highly correlated and should not function as independent variables in a regression analysis because they essentially measure the same thing. Patients who are underweight and qualify for a positive adjuster for low BMI are also subject to a BSA adjuster, which applies to all patients, including those with a low BMI. The BSA adjuster for low BMI patients is negative and offsets almost all of the benefit of the positive low BMI adjuster.

Thus, rather than continue adjusters that cancel each other out, KCP recommends that CMS rely upon the BSA adjuster to focus on patients who are overweight.

C. KCP continues to support right-sizing the outlier pool by allowing it to be less than 1.0 percent.

As noted in Section I of this letter, KCP remains concerned that CMS's calculations continue to overestimate the size of the outlier pool. This result has led to significant dollars being taken out of the system over the years. While CMS has consistently lowered the threshold for outlier eligibility, but that approach has not worked.

With calcimimetics being added to the bundle's base rate and qualifying for outlier payments, CMS has increased the size of the outlier pool for the first time. The Moran Company found that while IV calcimimetics appeared on only 8.4 percent of claims, they account for 74 percent of outlier-eligible claims. Claims without calcimimetics make up 72.6 percent of all claims, but only 21.2 percent of all outlier-eligible claims. Similarly, claims using only oral calcimimetics make up 18.8 percent of all claims, but only 4.5 percent of outlier-eligible claims.[17] This means that the outlier pool is now uniquely sensitive to changes in the utilization and price for calcimimetics. If there is a change in price or utilization, the outlier pool will be dramatically impacted.

We appreciate that CMS requests comments on alternative options for calculating the outlier pool withhold. KCP agrees that estimating the retrospective FDL trend using historical utilization data would provide a better calculation of the outlier pool withhold. The Technical Expert Panels (TEP) analyses have demonstrated that using utilization trends to project future thresholds would allow CMS to be closer to paying out a one percent outlier pool. However, this policy, as well as the current static model, assume a predictable environment. New innovative products are on the cusp of approval. They could receive TDAPA before being added to the bundle. These products will result in the historic curves not being a good match. Changes in utilization or price increases in the

[17]The Moran Company "2021 ESRD NPRM Decision Memo #3: Outlier Data" (*available upon request).*

products could move the thresholds in directions not anticipated when the withhold is calculated.

These exciting innovations will affect the use of the ESRD outlier services over time. They are some of the factors that make it difficult to anticipate changes in utilization over time and will be difficult to forecast accurately. As KCP has commented previously, nephrologists and facilities need two to three years of experience with a new product to understand how it can be effectively adopted. In addition, we want to make sure that patients who have needed the outlier pool historically are not shut out from it as these products come forward. The Moran Company estimates that only one percent of claims where no calcimimetics were used are projected to be eligible for outlier payments when calcimimetics came into the bundle. These factors affecting the outlier pool may be difficult to judge real-time and would likely have little precedent looking at historic trends.

CMS also proposes adopting a payment reconciliation option that would provide an add-on payment adjustment to address years when the outlier pool did not pay out fully and a "clawback" for years when the amount paid out exceeded that withheld. Based on our understanding of Medicare payment policy generally, this "true-up" process would be unprecedented in the Medicare program. With lags in the claims process and refiling of claims often over different calendar years, it could be difficult to calculate accurately such differences. Therefore, while KCP appreciates that this proposal attempts to address the concerns we have expressed about funding that is supposed to be directed to patient care being removed from the program, a payment reconciliation option seems like it would trade one problem for another.

Additionally, federal courts have historically struck down in the context of the hospital reimbursement system policies that sought to claw back overpaid outlier dollars or to settle claims. Given this line of cases, it is not clear that CMS has the authority to implement either the add-on or payment reductions contemplated in the RFI.

Given the concerns we have with the options in the RFI, KCP continues to advocate for CMS allowing the outlier pool withhold to be less than 1.0 percent. The statute does not create a floor, so CMS has sufficient authority to set the pool at or close to the amount it paid out during the previous years. Our recommendation for CY 2022 is an example of how this would work. Because CMS paid out 0.6 percent of the pool in the previous years, it should set the outlier pool at 0.6 percent for CY 2022. This policy allows for the flexibility of increasing the pool when necessary, avoids the disruption that could create problems for a trend analysis, and eliminates the risk of miscalculation of a payment reconciliation proposals.

The RFI also asks for comments on any anticipated effects enrollment changes in Medicare Advantage (MA) plans might have on the use of ESRD outlier services. To the extent that MA plans are not permitted to cherry-pick or lemon-drop patients, there would seem to be little impact on the outlier pool. However, as we have noted in previous letters,

KCP remains concerned that the decision to modify network adequacy standards that apply to nephrology care and completely eliminate network adequacy rules designed to protect patients' access to dialysis facilities will discourage many patients from enrolling in MA plans, especially those that might need more specialized treatment or require additional medications. To the extent this scenario were to occur, it could result in "outlier" patients remaining in traditional Medicare and the healthier patients enrolling in MA plans. At that point, the outlier pool could become skewed. We encourage the Part B and Part C groups to work together to make sure that MA plan networks include the providers and services that individuals who require dialysis need. We also encourage CMS to monitor the situation and work closely with the community to try to avoid this problem from occurring.

D. KCP supports ASPN's recommendation for the pediatric dialysis payment and cost reports.

KCP agrees with ASPN that the magnitude of total costs and pediatric multipliers do not reflect the total costs of ESRD care delivered to pediatric dialysis patients. Part of the reason is that pediatric patients require providers who specialize in pediatric care. There are additional costs associated with educating and training not only children (when appropriate), but also their parents and caregivers, including allowing for smaller staff to patient ratios that necessary for adult patients. Professional also include teachers and child life specialists that require additional resources to provide. Pediatric units must also stock not only standardized equipment, but also equipment that is tailored to meet smaller children.

ASPN and KCP agree that duration of treatment is not a valid proxy for the composite rate costs per treatment for pediatric care. We support ASPN's recommendation that a combination of age, weight, and pediatric-specific comorbidities be used as a proxy for composite rate costs. Comorbidities include:

- Failure to thrive/feeding disorders
- Congenital anomalies requiring subspecialty intervention (cardiac, orthopedic, colorectal)
- Congenital bladder/urinary tract anomalies
- Solid organ or stem cell transplant
- Neurocognitive impairment
- Global developmental delay
- Cerebral palsy
- Seizure disorder
- Chronic lung disease (and ensuing dependency on CPAP and ventilators)
- Inability to ambulate or transfer

Although all of these comorbidities significantly impact the provision of pediatric dialysis care, neurocognitive impairment and global developmental delay are often more longitudinally complex since they continue to pose significant management challenges even

as the child ages and there are not treatments or procedures that can readily ameliorate the underlying condition. Adolescents or young adults with profound neurocognitive impairment or global developmental delay continue to be complex despite their age and size and often require long-term a much more intense utilization of staff resources.

Because of the range of children who require dialysis, KCP supports ASPN's suggestion that the cost of care be broken into different age group categories: <6 years old, 6-11 years old, and 12-18 years old. Younger children may require more resources to treat than their older counterparts.

We also believe it is not appropriate to incorporate pediatric patients into the estimation of multipliers for both adult and pediatric populations. Given the extremely small number of pediatric patients, including pediatric patients as well as adults in the estimation of multipliers for both the adult and pediatric populations will result in multipliers that reflect only the adult population.

As CMS may recognize from other hospital cost report discussions, hospitals often triage their cost reporting obligations focusing on those that affect reimbursement over those that does not. This fact is true when it comes to pediatric dialysis costs as well. Despite efforts to educate reporting and billing staff, many hospitals have often made an administrative decision that the burden and complexity of reporting outweighs any revenue generated. As a result, they expend very few facility resources on collecting these data. Streamlining the reporting required and making it more consistent with reporting required from the state Medicaid programs or the private payers would improve the reporting.

KCP supports the suggested ASPN has recommended with regard to the pediatric dialysis cost report.

- Include Breakdown of Patient Age Groups (page 2, line 3):

3	Number of patients currently in dialysis program
a)	0-less than 6 years old
b)	6-11 years old
c)	12-18 years old
d)	19-25 years old (includes transition to adult care)
e)	26 years or older, if neuro-cognitive challenges/other medical challenges that require specialized care at pediatric center

- Pediatric-specific Supplies (page 4, line 9):

9	0900	Supplies*
10		Pediatric-specific supplies

- Pediatric-specific supplies includes pediatric dialyzer and special lines (pediatric, neonatal), Crit-Line for fluid removal monitoring, etc.
- Pediatric unit with percentage of patients over 15% would fill out pediatric line. (NOTE: This is to capture pediatric patients in adult units.)

- Facility Employees (page 2, lines 22-31): Add a sub-line for pediatric staff under the adult staff line

23	Registered Nurses
24	Registered Nurses with pediatric experience
25	Licensed Practical Nurses
26	Nurses' Aides
27	Technicians
28	Social Workers
29	Dieticians
30	Pediatric dietitians
31	Administrative
32	Management
33	Other (Specify)
34	Designated as a pediatric unit (>50% patients <18 yo)

We support updating the pediatric costs report to allow facilities to include costs that cannot be currently reported on the cost report, consistent with ASPN's recommendations.

E. KCP supports cost report reform, but the suggestions outlined in the RFI will not address the major issues with the current cost reports.

KCP appreciates that CMS is considering modifications to the cost reports; we believe these are long overdue. The cost report should be updated to reflect changes in policy, such as TDAPA and TPNIES. However, as noted in Section B addressing case-mix adjusters, cost reports are not an appropriate source of data for patient level costs, so any reform efforts should recognize that inherent limitation. In addition, cost report policy should also weigh the burden of data collection against the benefit to the system in collecting it. It is easy to ask for more data elements, but the more elements and the more complicated the instrument becomes, the more likely there will be errors. Given generally positive performance of the current cost report tool, we recommend targeting the modifications so that they reflect necessary changes and not overwhelm the system.

First, KCP asks that CMS update the cost report and the instructions to reflect the TDAPA and TPNIES policies. To support consistent reporting, we ask that CMS clarify at what time and on what lines dialysis facilities should record TDAPA and TPNIES

reimbursement amounts. Because these will be product specific costs and there could be multiple TDAPA or TPNIES in a single year, we recommend that CMS provide options so that individual products can be recorded on their own lines. There should also be the flexibility in the cost report that anticipates new products coming to market so that the cost report does not need to be amended in advance of each product's FDA approval.

Second, KCP is concerned about and does not support the contractor's suggestion to document costs on the basis of actual use rather than the current proportional allocation policies. We believe proportional allocation is the appropriate policy for both capital costs and labor costs. The TEP participants also voiced significant concern with this approach. Allocation is a fundamental concept for all Medicare payment systems. There has been no evidence to suggest that the current proportional allocation system misaligns costs or creates a problem. Given that this is a prospective payment system with a bundle, it is not clear how unbundling the items and services, such as gloves, masks, or tubing, would improve the payment system. The burden clearly outweighs any benefit, given that dialysis facilities would have to install new tracking systems, and the complicated proposals outlined in the TEP materials is practically unworkable in the real world. Therefore, we strongly recommend that CMS maintain the current proportional allocation policy.

Third, KCP appreciates the deep dive into capital and labor costs. However, the TEP contractor recommendations seek to add elements for which CMS already has the data on the cost reports. It is not clear how a different level of granularity will help improve the payment system, especially in a bundled environment. For example, in the labor category, the contractor proposes increasing the current number of labor categories to more than 100. Yet, when the bundled rate is set, it will rely upon the total rolled up number. There is no clear benefit for increasing the burden on dialysis facilities by parsing out more labor categories, when the information needed to evaluate payment rates is already available. In terms of capital costs, the cost reports already stratify costs by modality and in more detail that the alternative set forth in the TEP materials. As noted already, it is more appropriate to use proportional allocation methods than to tract actual costs across modalities.

In addition, the TEP contractor suggested changing the labor standards to the Bureau of Labor Statistics (BLS) NAICS codes for management and administration. KCP does not support this change. The BLS codes do not include many of the labor categories relevant to dialysis facilities, as the TEP contractor recognized by proposing additional categories. Second, the definitions of the categories are not clear and could lead to great confusion. The current Inpatient Prospective Payment System job categories, which are also used on other cost repots, align much better than the BLS codes and should be retained. We, similarly, do not support the shift to the BLS occupational categories for outpatient care centers for the same reasons noted already.

While it is true that labor costs are rising, adding complexities to the labor categories that could introduce confusion or inaccuracy in cost reporting is not the answer. As KCP as noted previously, State laws and work force shortages drive the increasing costs

for the most part. These costs are reflected by the existing cost data elements. However, they lag behind current costs significantly. Rather than rearrange the data elements, we ask that CMS address the problem by using more current wage data and evaluating the bundled rate each year using its authority under 42 U.S.C. § 1395rr(b)(2)(B) to assess the adequacy of the payment rate.

Similarly, KCP does not support the TEP contractor's suggestions related to supplies and lab costs. The TEP considered and rejected the idea of trying to break out the former composite rate supplies and labs between those that are for services that were composite rate services and those that were not. Non-ESRD related drugs, supplies, and labs, as well as those used with AKI patients, were not part of the composite rate. As such, there are no composite rate costs associated with these proposed categories. It does not make sense to try to perpetuate the former composite rate payment system in the cost report when the Congress eliminated it in favor of a single bundled payment amount.

Fourth, KCP reiterates our request that CMS allow facilities to include the 50 cents per treatment Network Fee on their cost reports. Consistent with our previous comments, this amount can be easily verified based on CMS-created documents already produced. The reduction in the rate should be taken into account when assessing the adequacy of the payment system, which cannot be done without the amount being included on the cost reports.

To achieve this goal, KCP recommends that CMS add the Network Fee as a revenue reduction on Worksheet D. CMS already includes the Network Fee on the PS&R, which facilities can use to obtain accurate and verifiable data, along with beneficiary coinsurance amounts. CMS addresses the coinsurance amount through Worksheet E, but the Network Fee is currently left off of the cost reports.

Given the reliance of the Congress and its advisory commission, MedPAC, on the cost reports for determining appropriate reimbursement policy, it is important that the cost reports include costs that are related to the care of Medicare beneficiaries. The Network Fee is such a cost. Without including that amount, policy-makers cannot calculate correct margins. It is in the interest of all policymakers that the information provided is as accurate as possible. Therefore, we encourage CMS to add the Network Fee on the facility cost reports beginning in 2022.

Finally, we support the suggestions to improve the instructions for the cost reports. This request goes beyond capital cost reporting instructions. We ask that CMS review with the community the cost report instructions through an informal guidance process and update them to provide clarity and consistency. KCP members would welcome the opportunity to review specific wording changes and suggest modifications to the instructions to support more consistent reporting by eliminating vague or confusing language that result in facilities interpreting the requirements differently.

F. KCP supports allowing individuals with AKI to select home dialysis.

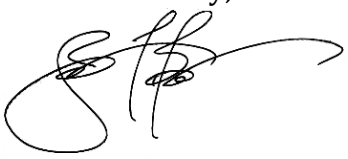
It has become clear that one of the complications of COVID-19 is AKI. The range of patients experiencing AKI is varied. The risk of AKI is 2-5 percent in certain papers, but as high as 19-23 percent for hospitalized or critically ill patients. As we noted in our comment letters on the COVID-19 Interim Final Rule, there are more AKI patients than ever before. To address this surge in patients, some hospitals have started these patients on home dialysis. Yet, once they are discharged, the rules of the Medicare program will not reimburse for these patients, because by regulation the reimbursement is limited to in-center dialysis. We ask that CMS reimburse providers for COVID-19 patients with AKI who are placed on home dialysis when hospitalized during the PHE.

The experience of the pandemic has shown the importance of the home dialysis modality. Thus, while we continue to ask CMS to provide an immediate waiver to allow AKI patients to select home dialysis during the PHE, we also believe that the clinical experience and data support expanding this option beyond the pandemic. The decision for individuals with AKI to select home dialysis should be a shared decision with the individual and the prescribing physician instead of being subject to a blanket prohibition. These patients would receive the standard training necessary for receiving home dialysis.

V. Conclusions

Thank you again for the opportunity to provide comments on the Proposed Rule. We appreciate the RFI and efforts to address many outstanding concerns KCP has raised about the ESRD PPS. We also believe that there are some of these recommendations that have been well vetted already and could be implemented for CY 2022; we encourage CMS to make these changes in the final rule. Please do not hesitate to reach out to Kathy Lester, our counsel in Washington, if you have any questions. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Ardelyx
American Society of Nephrology
AstraZeneca
Atlantic Dialysis
Baxter
BBraun
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
DialyzeDirect
Dialysis Patient Citizens
Dialysis Vascular Access Coalition
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
NATCO
Nephrology Nursing Certification Commission
Otsuka
Renal Healthcare Association
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma