



August 4, 2022

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

Re: CMS-1768-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.

Kidney Care Partners is a non-profit, non-partisan coalition of more than 30 organizations comprising patients, physicians, nurses, dialysis professionals, researchers, therapeutic innovators, transplant coordinators, and manufacturers dedicated to working together to improve the quality of care for individuals living with kidney disease.

In this letter, KCP provides comments on the following proposed policies:

- The options for a new policy to adjust the base rate for functional category drugs after the end of the transitional drug add-on payment amount (TDAPA) period;
- The ESRD market basket policies, including the annual update, rebasing, and revising the market basket using CY 2020 data;
- The revised definition of “oral-only drugs” and confirmation that CMS will apply TDAPA to phosphate binders and adjust the base rate after the TDAPA period ends if they are added to the bundled for 2025;
- AKI policies.

We plan to submit a second letter specific to the proposed PPS policies that will address:

- The outlier policy generally, as well as the proposed methodology for calculating the fixed-dollar loss amounts for adult patients;
- The TPNIES offset; and
- The case-mix and facility-level adjusters.

We will provide our comments on the ESRD QIP and ETC Model in separate letters as well.

KCP appreciates the ongoing opportunity to work with the Biden-Harris Administration as it seeks to improve access to high-quality kidney care and address inequities in the delivery of health care that those individuals living with kidney disease and kidney failure too often experience. As CMS notes in the preamble of the Proposed Rule, Fee-for-Service (FFS) “beneficiaries receiving dialysis are disproportionately young, male, disabled, and African- American, have low income as measured by dual status, and reside in an urban setting.”¹ These are the very individuals who have had to face the greatest and most severe inequities in the delivery health care. We reiterate our commitment to working with the Administration to address kidney disease prior to the time when an individual’s kidneys fail and they require dialysis or a transplant. We also continue to support efforts to improve access to transplants. As a community, we know that the best treatment option for patients is a transplant, but as this Administration has recognized, barriers in the current transplant system result in far fewer individuals with kidney failure receiving a transplant than those who need them.

While these pre-dialysis and transplant issues are important to address, it is essential to protect access to dialysis, given that more than 70 percent of individuals diagnosed with kidney failure require three-to-four-hour dialysis treatments at least three times a week in order to stay alive.² Addressing ongoing barriers within the current ESRD PPS is the key to transforming dialysis from a being primarily a life-sustaining treatment to a life-affirming one. We recognize that this Proposed Rule focuses on the traditional Medicare FFS program, but its impact reaches much further. The ESRD PPS not only sets payment for individuals who select FFS Medicare, but it is also the basis for the Medicare Advantage (MA) plan payments and innovative payment models, including the ETC and Kidney Care Choices (KCC) models. It is also the basis for reimbursement for services provided to individuals with AKI.

Given the foundational role of the PPS in Medicare, which also provides coverage to the vast majority of individuals living with kidney failure, it is important that the Administration continue its efforts to get these payment policies right. Getting the payment system right means supporting the long-term adoption of innovative treatment

¹87 *Fed. Reg.* at 38500.

² NIDDK. “Kidney Disease Statistics for the United States.” <https://www.niddk.nih.gov/health-information/health-statistics/kidney-disease> (Last Updated September 2021).

options, making sure incentives to adopt innovation apply to patients enrolled in MA plans, targeting case-mix and facility-level adjustors, outlier policies, and similar policies to prevent millions of dollars being trapped within the federal government and not spent on patient care, and providing flexibilities that support care coordination among those health care providers who provide services to individuals living with kidney disease and kidney failure.

KCP strongly supports many of the proposals outlined in the Proposed Rule and offers recommendations for improving and refining others. We look forward to continuing to work with the Administration to get the ESRD PPS right.

I. KCP Urges CMS to Propose and Adopt an Add-on Payment Adjustment for New Drugs and Biological Products Assessed to Be within Existing ESRD PPS Functional Categories after Their TDAPA Period Ends.

KCP thanks CMS for recognizing the kidney care community's concerns about the current blanket "no new money" policy restricting any adjustment to the ESRD PPS payment rate when a new drug or biological enters the bundle in an existing functional category at the end of the TDAPA period. In this letter, KCP provides our initial comments on the policy options and how the policy could be designed. We plan to provide additional feedback in the near future as well and would welcome the opportunity to continue the dialogue with CMS after the comment period given critical importance of getting an appropriate policy implemented in a timely manner. Thus, we offer comments to the specific questions in the RFI below and recommend the following.

- CMS should support the long-term adoption of innovative products by adjusting the PPS payment rate after the TDAPA period ends for new drugs and biological products CMS determines are within an existing ESRD functional category. This needs to be new money and not budget neutral to the current system, which we believe is consistent with the wording of the options in the preamble.
 - KCP has historically asked for an adjustment to the base rate, but also supports adopting an add-on payment adjustment methodology.
 - KCP believes that a benefit of an add-on adjustment is that it eliminates the need to remove the additional monies from the adjustment due to the PPS adjustment factors and wage adjustment. This creates a closer nexus between the add-on amount and the cost of the product.
 - KCP also supports an add-on adjustment because it creates the right balance needed to ensure that there are sufficient dollars to meet the needs of individuals patients who require a particular product, especially in cases where a product may not be used by the "average dialysis patient." It is consistent with the language in S. 1971/H.R. 4065 "Chronic Kidney Disease Improvement in Research and Treatment Act of 2021," which would require the Secretary to establish a methodology to adjust the single payment amount so that the dollars follow the administration

- of a drug or biological to the patient. While a drug that is used by the average patient or vast majority of patients may be supported by adding dollars directly to the base rate, using that method for a new, higher-cost product that is used by a much smaller percentage of patients, may not best direct funding for patient care.
- The add-on adjustment establishes a payment amount based on the per treatment cost for the average patient using the product. In that way, it is not “unbundling the bundle,” but rather recognizing that for patients who require a particular product the current base rate is not adequate to support the provision of that product. Because the amount is an average per treatment amount, it differs from a pass-through policy that removes an item from a bundled payment system. We also assume and would support that there is no limitation on the total expenditures made for the drug or biological, so long as the provision of it is medically necessary.
 - KCP supports offsetting the amount of the add-on adjustment by an amount that corresponds with the reduction in expenditures for other formerly separately billed renal dialysis drugs that were caused by the inclusion of the new product.
 - The reduction in utilization of a product should be based on objective, clear, transparent data from available public claims data.
 - The attribution of the reduction to a specific product(s) should be determined by reference to a predictable, objective, and transparent source, such as the FDA approved indication for each product expressly listing the same primary indication.
 - KCP does not support an offset for the reduction in the expenditure per treatment across all other formerly separately billable renal dialysis drugs and biological products. The offset should be linked using empirical data that the change in expenditures is directly attributable to the adoption of the new product.
 - KCP also recognizes that fiscal responsibility dictates having some sort of offset and not adding the per treatment cost of a new product to the payment rate when the empirical data show that adoption of the new product can be attributed to a decrease in the utilization of a formerly separately billed drug or biological.
 - KCP supports calculating the cost of the TDAPA product as the average expenditure per treatment of the renal dialysis drug or biological product that was paid for using the TDAPA.
 - This determination should be made using at least two full years of utilization and price data collected during the TDAPA period, which means the TDAPA period would likely need to be at least three years.
 - KCP supports calculating the reduction in expenditures for formerly separately billed drugs that meet the attribution criteria using the difference between these

expenditures in the most recent year with claims data available and the expenditures in the current base year for the market basket. These data should be made public as well.

- As noted below, KCP supports rebasing the ESRD market basket using CY 2020 data.
- KCP urges CMS to update the add-on adjustment annually to account for inflationary changes. This could be done using the current ESRD market basket, for example, or proxy indices specific to these types of drugs.
- KCP urges CMS to allow the adjustment to be paid out immediately upon the expiration of the TDAPA period for a product to avoid a gap between the TDAPA and availability of the post-TDAPA add-on adjustment.

Given that the first TDAPA drug within an existing functional category launched earlier this year, we are pleased that CMS has sent the clear signal that it recognizes the concerns with the current policy that could stifle the adoption of new functional category products. It is particularly important for CMS to be clear that this policy will be available for KORSUVA® given its importance to patients with CKD-associated pruritis who have had to live with a long-standing gap in treatment for this disease. However, it is still necessary for CMS to propose and implement this policy. Therefore, we urge the Biden-Harris Administration to propose the add-on adjustment policy consistent with KCP's recommendations as part of the CY 2024 proposed rule.

Response to Specific RFI Questions

- 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?

Yes, an add-on payment adjustment for new drugs and biologicals that come within existing functional categories after the TDAPA period ends is necessary to protect access to these innovative products. As we have noted in previous letters, the ESRD PPS bundle rate was set using the previous composite rate (which included certain drugs commonly provided in dialysis facilities) and ten drugs and biologicals that were separately billable prior to the implementation of the ESRD PPS, thus reflecting pharmaceutical options available ESRD beneficiaries before 2008. As a result, ESRD beneficiaries lack the access to innovation compared to their non-ESRD peers. This result is extremely troubling given that the overwhelming majority of dialysis patients are Black and Brown and already experiencing other inequities in the delivery of health care.

Based upon the information CMS shared when it bundled these products together, The Moran Company has determined the current amounts of spending in the current functional categories.

The Moran Company has found there are very few dollars in the majority of the categories. Practically speaking, the existing dollar values would not support a dialysis facility incorporating even the most modestly priced new products into the base rate.

As discussed in preamble, CMS has indicated in the past that it believes the outlier pool coupled with the annual market basket update would address any short-fall in funding. However, these policies are not designed to reimburse new products that are added to the bundle, especially when the base funding amounts are as low as The Moran Company has indicated. The outlier pool is not designed to reimburse for the provision of drugs or biologicals; it is designed to address the significantly higher costs of those patients whose medical needs require the administration of certain products.

For example, if the outlier pool were used instead of an add-on adjustment, the proportion of the outlier payments associated with patients receiving any new drug would likely increase so substantially that the current base rate would be eroded. 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. The problem would be substantially worse if there were no adjustment to the rate to cover the cost of the average patients receiving the new drug or biological.

Without an add-on adjustment to the base rate, the outlier pool would no longer serve its desired purpose. Those patients the outlier pool was designed to protect would be left behind. Additionally, because the outlier policy is budget neutral, the average dialysis patients would also be harmed because the dollars intended to cover the cost of their treatments would necessarily be cut. Because the overwhelming majority of individuals who rely upon dialysis are from communities of color who already experienced severe inequities in the delivery of their health care, it is important that Medicare's reimbursement policies are not contorted to exacerbate this problem. Relying on the outlier policy to cover the cost of new products entering the bundle would expand the inequities in the delivery of health care that the Biden-Harris Administration otherwise seeks to eliminate.

Similarly, the ESRD market basket updates also cannot ensure that the PPS reimbursement rate will be adequate to support the adoption of new products. As The Moran Company analysis has shown, the amounts in the current base rate as the basis of reimbursement for new products in functional categories are woefully inadequate to support the cost of new drugs as noted already. In addition, the drug proxy used historically for updating the base rate for non-ESA drugs and biologicals has been the PPI

Commodity for Vitamin, Nutrient, and Hematinic Preparations (BLS series code #WPU063807). As KCP has noted in previous letters, the vitamin proxy has not appropriately captured the price of the majority of non-ESA drugs that fall within the functional categories. The drugs within the vitamin proxy represent a small portion of the overall cost of providing dialysis services. As noted elsewhere in the letter, KCP is pleased that CMS has proposed to add the PPI Commodity for Pharmaceuticals for human use, prescription (BLS series code #WPUSI07003) (although we believe CMS should monitor it and adjust the weighting if needed). However, the inadequacy of the previous proxy means that it would be inappropriate for CMS assume that the base rate is sufficient reimbursement for new innovative items when they are added to the bundle.

Given these concerns, KCP reaffirms the need for an add-on payment adjustment for new drugs and biologicals that come within existing functional categories after the TDAPA period ends to patient protect access to these innovative products.

- 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?

First, we agree that all new drugs or biologicals that receive TDAPA and CMS finds are within existing functional categories should receive an incremental add-on adjustment. Two full years of claims data should be used to establish the utilization of the product, which will require at least a three-year TDAPA period. At least two full years of data are necessary as we have noted in previous letters because even with all of the right incentives in place, it can take some time for physicians to determine how best to use a new product with their patients. This is why the hospital pass-through payments are provided for three years. CMS also used this rationale when it provided TDAPA for three years for the calcimimetics. It is important to provide these new functional category drugs and biologicals with at least three years of TDAPA as well, so that CMS has sufficient data (at least two full years of data) to calculate the drug add-on.

In terms of determining cost, we support using the most recently available Average Sales Price. This approach aligns with how CMS established the initial base rate when adding formerly separately billed drugs and its policies related to calcimimetics and new drugs not within a functional category.

Second, we agree that the scope of drugs and biologicals considered for the offset analysis should be formerly separately billed drugs and biologicals. There is no current or prior tracking data of drugs that were in the original composite rate, making it difficult if not impossible to accurately assess their historic utilization as a basis for comparison. CMS should also ensure that current and future reporting systems provide valid information with which to make the required calculations for formerly separately billed drugs and biologicals. For example, current CMS policies that require the reporting of certain oral

drugs based on the number of pills, compared with the prior reporting of dosage units, would not be suitable as the basis for the calculations under consideration by CMS.

We also support that the comparison to establish a link between a change in the utilization of the formerly separately billed drug or biological and the new TDAPA product be based on reference to a predictable, objective, and transparent source. Just as CMS relies upon the FDA approved indication for determining whether a product fits in within an existing functional category, it should rely upon the FDA-approved primary indication to assess whether an existing product's change in utilization during the TDAPA period of a new product is clearly attributed to physicians prescribing the new product in lieu of prescribing the existing product. This direct attribution analysis is important because changes in utilization may occur during the TDAPA period of a new product, but not be related to the adoption of the new product. For example, a new product may be additive to the existing products, but changes in utilization could occur because of manufacturing shortages or supply chain problems. Changes in expenditures might not be due to changes in utilization, but a generic coming to market that is in no way related the new product. It is important that CMS use clear, objective data to determine whether the change in utilization that ultimately changes the per treatment expenditures for the existing drug or biological be directly attributed to the adoption of the new drug or biological.

- 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? Please provide as much detail as possible.
 - Are there other methodologies that CMS should consider? Please provide as much detail as possible.

KCP agrees with the premise that CMS should compare the expenditures of formerly separately billed drugs and biologicals and the new product receiving TDAPA to assess the amount of the add-on adjustment. The comparison should be based on objective, transparent data that demonstrates a direct link between the formerly separately billed drug within the functional category and the new TDAPA product. Just as CMS relies upon the FDA-approved indication for determining whether a product fits within an existing functional category, it should rely upon the same information for making the comparison.

First, KCP believes that Options 1 and 4 will not work for CMS or the kidney care community; we also agree that an add-on amount should be incremental in nature. Option 1 is not viable given the high potential for confounding. Specifically, changes in utilization of other drugs may occur during the TDAPA period of a new product, due to other unrelated circumstances aside from the adoption of the new product. For example,

changes in utilization could occur because of manufacturing shortages or supply chain problems or effects of the public health emergency (PHE). Option 1 also would essentially function as a recalibration of the ESRD PPS base rate any time the TDAPA period ends for a new drug or biological within an existing functional category. However, we believe that given the historic and ongoing underfunding of the ESRD benefit, which is relied upon primarily by Black and Brown patients, any offset to a new money add-on adjustment be directly attributed to the addition of the product to the bundle. This direct attribution approach will protect the integrity of the bundle and ensure that the needs of the average patient are not sacrificed for the needs of patients who benefit from the new product.

While Option 4 is attractive in many ways, KCP acknowledges that Option 4 is not appropriate to fail to account for dollars already in the functional category when a new drug or biological's adoption can be objectively determined to reduce the utilization of existing drugs already paid for under the bundle.

Second, Options 2 and 3 provide for an incremental add-on amount, but differ in the type of evidence used to determine the reduction in the add-on amount. It is not clear how CMS defines the phrases "empirically attributed" and "data-driven based on end effect to be attributed." We agree that the evaluation of formerly separately billed drugs should include an analysis of whether the change in expenditures in these products is attributed the adoption of the new TDAPA product. The framework used to establish the clinical association should be the primary indication on the FDA label coupled with a statistically significant difference in the utilization in the formerly separately billed drug or biological during the TDAPA period of the new drug or biological. The criteria should not require additional studies or language from FDA or require comparative or similar types of studies. If this link is established, then CMS should evaluate whether there has been a change in utilization of the formerly separately billed drug or biological that is statistically associated with the use of the new TDAPA product during the TDAPA period. The data used for determining utilization should be dialysis claims.

As we noted in the introduction to this letter, we urge CMS to review these comments and continue to work with KCP and its members to allow the Agency to propose a policy for CY 2024 in next year's rulemaking given the urgent need for the pathway to be clearly defined.

KCP appreciates the opportunity to provide these initial comments on the RFI and voice our strong support for CMS to act quickly and thoughtfully to protect access to innovative products for individuals who rely upon dialysis and the Medicare program. We look forward to providing more detailed recommendations in the near future.

II. KCP Supports Rebasing and Revising the Market Basket Using CY 2020 Data and the Adoption of the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code #WPUSI07003) Drugs/Biologicals.

A. KCP Supports the Recommendation to Rebase and Revise the ESRD Market Basket Base Year to 2020 and Proxy Changes.

KCP appreciates that CMS recognizes that the market basket assumes there is a constant mix of goods and services to provide renal dialysis services and that the prices of the goods and services fluctuate over time. The primary way to address changes in the mix of these goods and services is to rebase to a more current year. We agree that the data from 2016 no longer reflect the current mix of goods and services adequately. Therefore, KCP supports rebasing the market basket using CY 2020 data. We thank CMS for including the impact of the proposed rebasing on the weights in the major cost categories and agree with the percentages outlined in Table 1 of the Proposed Rule. We also support the proposal to disaggregate the Administrative & General major cost category to create more accuracy in the reporting of costs ESRD that facilities incur.

KCP also supports the decision to adopt the PPI Commodity for Pharmaceuticals for human use, prescription (BLS series code #WPUSI07003). However, we believe that the vast majority of the non-ESA drugs in the ESRD PPS bundle align with this proxy and not the PPI Commodity data for Chemicals and allied products-Vitamin, nutrient, and hematinic preparations, not seasonally adjusted. Thus, KCP suggests that CMS monitor the impact of this change and adjust the weight of the vitamin proxy in future years if appropriate.

KCP also supports the increase of the labor share from 52.3 percent to 55.2 percent. Our members report the costs of labor are rising exponentially. However, shifting the market basket percentage alone will not address the crisis. In subsection D, we offer an option for addressing the gap in the market basket due to the labor crisis to protect patient access to dialysis treatments.

B. KCP Supports the Proposed Cap on the Wage Index Changes to Promote Predictability.

The wage index continues to raise concern among many KCP members. Even though a broader conversation around the wage index and the implications of the budget neutrality requirement should be undertaken, we thank CMS for recognizing the need for greater predictability to avoid negative impacts on facilities. We support applying a five percent cap on any decrease to an ESRD facility's wage index from its wage index in the prior year, regardless of the circumstances causing the decline.

C. Recognizing that CMS Does Not Have Authority to Eliminate the Productivity Factor, KCP Notes Its Concerns with the Continued Application of It to Cut the ESRD PPS 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 historically small and even negative Medicare margins and the experience of dialysis facilities argues against the idea that productivity can be improved year-over-year.

D. KCP Requests that CMS Update the Base Rate to Reflect Errors in the Projection Used to Update the ESRD PPS Base Rate in Previous Years.

KCP appreciates CMS including Table 8 in the Proposed Rule to show the forecasted and actual market basket for CYs 2019-2023. In reviewing this chart, The Moran Company highlighted that the contractor forecast a 1.6 percent increase in CY 2022 costs and finalized an increase of 2.4 percent based on the more recent data available at that time. However, Table 8 indicates that the actual market basket increase should have been 4.5 percent for CY 2022, if historical data had been used. Had the forecast been correct, the 2022 base rate would have been \$263.21. If CMS were to correct this forecasting error now, the 2023 proposed base rate would be \$269.53 rather than the proposed \$264.09. A similar analysis is true for CY 2021.

As KCP noted in a letter to CMS in April 2022, KCP members are experiencing a labor crisis that is having a negative impact on patient access to care. Without sufficient staff available, facilities are eliminating shifts, closing early, or not being available on certain days of the week because they cannot find the nurses and technicians they need to safely operate. In the April letter, KCP requested that CMS use its existing authority to establish a temporary adjustment to support facilities as they bear the additional costs that the workforce shortage has required them to incur to protect beneficiary access to dialysis.

One way to determine the amount of the adjustment could be to apply the actual percent increase in the market basket for the two calendar years where the forecast dramatically missed its mark. CMS has applied this type of an adjustment in other parts of the Medicare program historically and could do so for the ESRD PPS in a temporary manner. While adding these dollars might not address all of the costs incurred because of the labor crisis, it would infuse desperately needed funds into the program to allow facilities to offer competitive salaries and benefits to the health care professional they employ to provide dialysis services to individuals requiring dialysis treatments. These are extraordinary times due to the ongoing pandemic, and they require creative solutions to support individuals relying on Medicare for their dialysis services.

- III. KCP Continues to Recommend that CMS Not Incorporate Oral-Only Drugs into the Bundle after the Current Statutory Restriction Expires, but Supports Applying TDAPA to Phosphate Binders and Adjusting the Base Rate after TDAPA Period Ends, if CMS Were to Add Them. KCP Recommends that CMS Clarify the Definition of “Oral-Only Drugs.”**
- A. KCP Recommends Continuing to Exclude Phosphate Binders and Phosphate Lowering Drugs in the Bundle, but If They Are Included, Requests that CMS Re-Affirm that It Will Apply TDAPA to These Products and Add New Money to the PPS Rate.**

KCP members continue to have practical implementation concerns about adding oral-only products to the ESRD PPS. The preamble to the Proposed Rule indicates that CMS plans to incorporate phosphate binders and phosphate lowering drugs into the bundle as early as January 1, 2025.

As we have noted in previous letters, we remain concerned that adding phosphate binders and phosphate lowering drugs to the bundle will have a negative impact on patients. Phosphate binders and phosphate lowering drugs must be taken outside of the facility and when a patient eats. The dosage is difficult to manage because it can vary with the size of snacks and meals that a patient consumes. The correct regulation of these medications can be difficult because there is no “average” patient when it comes to dosing these drugs. While we understand that MedPAC has suggested incorporating these products into the bundle, this assessment does not correspond with the clinical realities that health care providers and individuals who require these products actual experience. The Congress recognized the challenges of including these drugs in the ESRD PPS when it has repeatedly restricted CMS from adding them.

We believe the same concerns that led to the Congress to keep these products out of the bundle continue to exist. Therefore, we are concerned about statements in the preamble to the Proposed Rule suggesting that CMS plans to add phosphate binders and phosphate lowering drugs to the bundle in 2025. We ask that CMS take into account the difficulty in administering these drugs to meet the very specific needs of each patient and exercise its existing authority to permanently exclude or further delay the inclusion of oral-only drugs that are furnished for the treatment of ESRD. CMS’ authority to do so is clear. The statute does not mandate their inclusion in 2025. It only prohibits CMS from including them prior to 2025. We believe permanent exclusion or further delay of these products would benefit beneficiaries who require these drugs, relieve burden on providers, and benefit the Medicare program.

If CMS were to decide to include phosphate binders and phosphate lowering drugs in the base rate for 2025, KCP asks CMS to affirm that regardless of the existence of an IV-equivalent, it will implement a transitional add-on adjustment period to assess the utilization and cost of these products before adding them to the bundle and that CMS will

add new money to the bundle rate once they are added. We believe that the statements in the Proposed Rule³ suggests the application of this policy, but ask CMS to affirm our understanding. The TDAPA period is necessary because, as CMS recognizes, it did not include the cost for oral drugs in the ESRD PPS base rate when it created the bundled rate and Part D data is incomplete. 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. It is consistent with CMS' statements that "the TDAPA helps ESRD facilities to incorporate new drugs and biological products and make appropriate changes in their businesses to adopt such products, provides additional payments for such associated costs, and promotes competition among the products within the ESRD PPS functional categories."⁴

B. KCP Appreciates the Proposal to Clarify the Definition of "Oral-Only Drugs," but Seeks an Important Clarification.

KCP supports CMS's efforts to clarify the definition of "oral-only drugs"; however, we would be concerned if CMS were to apply the concept of functional equivalence implied by this definition change across the entire functional category. We recommend that CMS clearly state that the end action effect definition applies more narrowly within the categories to the classes of products within the relevant functional category.

In addition, we recommend that to the extent CMS proposes and adopts a policy to adjust the payment rate for products within a functional category once their TDAPA period ends, as is being considered under the RFI, that the agency apply this policy to the bone mineral metabolism category as well. We raise this request in light of language in the preamble that suggests CMS would not adjust the base rate for new products that might come within this particularly functional category.⁵

As CMS recognizes in the preamble, it is critically important to make sure that Medicare policies promote access and avoid perpetuating existing health inequities. To that end, CMS should ensure that there is sufficient funding in the ESRD PPS to protect access to all medically necessary medications needed by individuals who require dialysis and rely upon Medicare to receive it. In addition, the desire to bundle services should not create new barriers to accessing products that patients have become accustomed to receiving through the Medicare Part D, Medicaid, or similar programs.

³*Id.* at 38496.

⁴*Id.* at 38522

⁵*Id.* at 38499-50.

IV. KCP Urges CMS to Allow AKI Patients to Select Home Dialysis Modalities and Eliminate the Current Prohibition; KCP Requests that CMS Share the Results of the Monitoring Effort.

KCP and our members remain committed to supporting home dialysis modalities for those individuals living with kidney failure. Our support extends beyond those diagnosed with ESRD to those living with AKI. However, current Medicare rules do not cover home dialysis for AKI patients because the payment regulations limit individuals with AKI to receiving in-center dialysis. We ask that CMS remove this barrier and allow physicians, individuals with AKI, and their care partners to have the option of selecting home dialysis.

Since Congress expanded treatment options for those living with AKI to include dialysis facilities, clinical understanding of AKI has advanced. Initially, CMS expressed concern about AKI patients receiving dialysis at home, particularly peritoneal dialysis (PD). However, during the pandemic many patients who developed AKI received home dialysis successfully. The initial safety concerns that underly the current policy have been shown to be unwarranted.

Both professional nephrologist societies, the Renal Physicians Association and the American Society of Nephrology, agree that AKI patients can safely receive dialysis at home via PD or home hemodialysis (HHD). In particular, RPA supported AKI patients having access to all types of modalities in its 2016 position paper, *Acute Kidney Injury Patients Requiring Outpatient Dialysis*.⁶ RPA has also stated: “In light of the increased emphasis on expanding access to home dialysis in general and the increasing number of programs utilizing emergent or urgent peritoneal dialysis as opposed to hemodialysis as rescue therapy for patients presenting in urgent need, excluding such patients from coverage seems counter to the shared goal.”⁶ KCP agrees.

The current policy restricting access to home dialysis modalities for AKI patients also perpetuates the current inequity in the use of home dialysis among people of color. Black Americans are more likely than White Americans to experience AKI.⁷ As a result, the federal policies prohibiting AKI patients selecting home dialysis modalities expands the existing gap in Black Americans with kidney failure selecting home dialysis.

KCP urges CMS to eliminate this unnecessary barrier to home dialysis for individuals with AKI.

Additionally, KCP requests that CMS release the data it has gathered while monitoring the AKI benefit. The clinical success of expanding access to AKI services is

⁶RPA. “RPA Comments on the 2017 ESRD PPS Proposed Rule Including AKI Policy” <https://www.renalmd.org/page/ESRDPPSRuleComments?> (2016).

⁷Grams ME, Matsushita K, Sang Y, Estrella MM, Foster MC, Tin A, *et al.* “Explaining the racial difference in AKI incidence.” *25 J Am Soc Nephrol* 1834–41. (2014).

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unquestioned. However, it is less clear whether the payment policies designed to support individuals living with permanent kidney failure and receiving dialysis are adequate to support the services that AKI patients require. KCP understands that CMS continues to monitor the AKI benefit, and we ask that CMS make this monitoring data publicly available to allow the community to combine it with the clinician and patient experiences to better understand the impact of relying upon the Medicare ESRD payment policies for the AKI benefit.

V. Conclusion

Thank you again for the opportunity to provide comments on the Proposed Rule. Our counsel in Washington, Kathy Lester, will be reaching out to schedule a meeting, but please do not hesitate to reach out to her if you have any questions in the meantime. She can be reached at klester@lesterhealthlaw.com or 202-534-1773.

Sincerely,



John Butler
Chairman

cc: Elizabeth Richter, Deputy Director
Jason Bennett, Director, Technology, Coding, and Pricing Group
Ing Jye Cheng, Director, Chronic Care Policy Group

Appendix: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Society of Nephrology
American Society of Pediatric Nephrology
Ardelyx
AstraZeneca
Atlantic Dialysis
Baxter
Cara Therapeutics
Centers for Dialysis Care
Cormedix
DaVita
Dialysis Patient Citizens
DialyzeDirect
Dialysis Vascular Access Coalition
Fresenius Medical Care
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
U.S. Renal Care
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma