



September 11, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–6082–NC
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: CM S-1713-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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements

Dear Administrator Verma:

As a prelude to our comments on the payment provisions of the CY 2020 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) proposed rule (Proposed Rule),¹ Kidney Care Partners (KCP) would like to reiterate our support and appreciation of the Administration’s focus on patients living with chronic kidney disease and kidney failure. Since its establishment in the early 2000s, KCP and our members have sought to increase awareness and understanding among policymakers at both the Federal and State levels to improve the lives of kidney disease patients and to try to end the reign of kidney disease as one of the leading causes of death in the United States. We look forward to working with the Administration to help achieve the overarching goals outlined in the Department of Health and Human Services (HHS) “Advancing American Kidney Health.”

We strongly support the three primary objectives of the initiative: (1) increasing efforts to prevent, detect, and slow the progression of kidney disease; (2) providing patients with kidney disease with more options for treatment; and (3) delivering more organs for transplant.² In this letter related to the ESRD PPS, KCP offers suggestions centered on the second goal of improving access to, and the quality of, person-centered treatment options.

¹84 Fed. Reg. 38330 (Aug. 6, 2019).

²HHS, “Advancing American Kidney Health” 3 (July 2019).

For HHS to achieve these goals, it is critically important that the ESRD PPS adequately reimburse facilities for the care being provided. Currently, and as MedPAC has recognized, the ESRD PPS payment rates do not cover the cost of providing the required services to patients. Therefore, KCP's recommendations and suggestions seek to refine the current PPS so that it becomes sustainable. Specifically, KCP asks the Centers for Medicare & Medicaid Services (CMS) to:

- Adopt a sustainable pathway for drugs and biological products that qualify and receive TDAPA to be added to the ESRD bundle after the TDAPA period ends, which would include providing an incremental adjustment to the base rate if the current dollars are not sufficient to cover the cost of providing the product.
- Finalize, with one modification to allow a product with its first ESRD-related indication to also qualify for TDAPA, the use of NDA Types proposed to determine which drugs or biologicals should receive TDAPA and the exclusion of generics, as well as biosimilars, from TDAPA eligibility.
- Set the base for TDAPA at ASP+6 percent.
- Finalize the proposed transitional add-on for truly innovative devices, but establish the transitional period to allow for the collection of two full calendar years of data, provide a long-term sustainable pathway for adopting such devices by appropriately adjusting the PPS base rate when these products are added to the bundle, work with the community to establish a transparent structure around the process the MACs will use to set list price, and extend the application deadline.
- Work with KCP to propose in the next rulemaking a pathway for accounting for new capital equipment in the ESRD PPS.
- Finalize the extension of TDAPA for calcimimetics for a third year, but continue to use ASP+6 percent as the basis for TDAPA.
- Refine the ESRD PPS case-mix and facility-level adjusters.
- Revise the outlier policy.
- Address other technical issues outlined in Section III.

I. Refining the ESRD PPS To Support Innovative Options for Treatment

In the "Advancing American Kidney Health" report, HHS defines one of the objectives of the goal of providing patients with kidney disease with more options for treatment as

“introduc[ing] new value-based kidney disease payment models that align health care provider incentives with patient preferences and improve quality of life.”³ As part of this objective, HHS indicates that “Medicare will continue to support payment rule changes for the ESRD PPS that focus on patient care, support innovation, reduce burdens, and lower costs.”⁴ It further outlines three actions that the CMS is taking to help support innovation in the ESRD PPS.

- CMS is considering ways to encourage ESRD facilities to furnish new and innovative drugs and biological products for the treatment of ESRD. The Transitional Drug Add-on Payment Adjustment (TDAPA) is an add-on payment adjustment under the ESRD PPS intended to facilitate this goal for Medicare beneficiaries. This is done by encouraging ESRD facilities to furnish certain qualifying new renal dialysis drugs and biological products by allowing additional payment for them while utilization data is collected.
- CMS recognizes that continual refinement of the ESRD PPS is necessary to benefit people living with ESRD, and is therefore working with an analytical contractor to perform payment analysis and develop potential refinements to the ESRD PPS. CMS plans to ask for stakeholder input on data collection.
- Based on comments received during and after the CY 2019 ESRD PPS rulemaking, CMS is considering issues related to payment for new and innovative supplies and equipment that are renal dialysis services furnished by ESRD facilities for ESRD beneficiaries.⁵

As we had raised in our comments on the CY 2019 ESRD PPS (dated August 10, 2019, and August 23, 2019), there are two parts to incentivizing new and innovative drugs, biological products, and devices in any payment system. The first part is how to encourage adoption during the first few years after an item is introduced; the second part is establishing a long-term pathway that adjusts the payment rate to adequately reimburse the item once it is folded into the bundle. While we have recommended, and will continue to do so in this letter, modifications to TDAPA and the proposed add-on for truly innovative devices, we support the concept of transitional add-ons as the first part of the two-part policy for encouraging the adoption of new and innovative products in the ESRD PPS. We also call, once again, on CMS to implement a policy for all new and innovative products, regardless of their functional category status, that will adjust the ESRD PPS when such products are added to the bundle as the second part of this policy.

³*Id.* at 15.

⁴*Id.*

⁵*Id.* at 16.

A. Payment policy recommendations to support new and innovative drugs, biologicals, and devices after the transitional period.

Transitional payments alone are not sufficient. The Proposed Rule seems to continue a no new money policy for certain drugs and biological products that fall within the ESRD PPS's functional categories. A similar policy seems to be proposed for truly innovative new devices as well. As we understand these policies, CMS will not adjust the bundled rate when functional category drugs or biological products or devices are added to the ESRD PPS. Yet, the second and third bullet under Objective 2 in the "Advancing American Kidney Health" suggests that HHS recognizes that the ESRD PPS requires additional refinement and may be considering ways to address the incorporation of new products, including functional category drugs/biological products and devices, into the ESRD PPS. KCP sincerely hopes that this is in fact the case. To the extent that is true, we urge CMS to indicate that it is taking this pathway in the final rule for the CY 2020 ESRD PPS.

As we have stated in numerous meetings and previous comment letters, the ESRD PPS is underfunded – it costs more to provide the necessary services to Medicare patients than the amount that Medicare reimburses facilities to provide these services. MedPAC continues to recognize this fact as part of its annual *Report to the Congress*, each of which has highlighted the ongoing negative Medicare margins experienced by dialysis facilities. Thus, while a temporary add-on provides new money for two to three years or more, it does nothing to address the underfunding of the program or provide a sustainable pathway for the permanent adoption of new products.

Without a sustainable pathway, facilities simply cannot afford to adopt new and innovative products that will, in many cases, be more expensive than those currently in the bundle's functional categories. The chart below, prepared by The Moran Company, illustrates the problem.

**Table A: Dollar Amounts for ESRD Bundle Drug
 for Functional Categories Other than Anemia Management on a Per Treatment Basis
 (Source: The Moran Company analysis of CMS data)**

	2017 Utilization by Facilities Priced at ASP+6
Functional Category	Avg. MAP per Tx
Bone and Mineral Metabolism	\$ 1.09
Cellular management	\$ 0.02
Access Management	\$ 0.18
Anti-infective	\$ 0.12
Other injectables	\$ 1.37

The limited number of dollars available in the existing functional categories results from the lack of innovation in the most basic areas of kidney care during the last three decades. Like CMS, KCP supports the concept that a bundled payment should promote competition. However, even the most judiciously priced new product cannot compete against products that the bundle covers at \$1 or less. The rate will need to be adjusted, if CMS wants to ensure that new products are available after the transitional period.

Likewise, KCP agrees that CMS should not necessarily be in a position where it adds new money every time a new product is added to the bundle. However, a blanket no new money policy swings the pendulum too far in the other direction. For this reason, KCP had recommended that CMS adopt guardrails to define when a drug or biological product is truly innovative, which will limit the cost of TDAPA. If a product qualifies under those guardrails, it should receive TDAPA. During the TDAPA period, CMS would collect the data it needs to determine whether the current bundled rate is sufficient to allow the new product to fairly compete in the bundle or if cost and utilization of the drug or biological product would require dollars to be added to the base rate. As noted below, the money saved under this policy (which is similar to the proposed use of NDA Types) should be used to support adjusting the bundled rate for truly innovative products when they their pass-through period ends.

KCP suggested an additional safeguard, as well, for those drugs that are not used by the average patient. In those cases in which a product is used by a smaller percentage of the ESRD population, CMS would bundle the product, but instead of spreading the dollars added to the base rate across all facilities, CMS would establish a pool from which facilities using the new product would be paid if they administered the product to a specific patient. The pool along

with the base rate would be modified each year under the market basket methodology. It would not be a separate add-on outside of the bundled rate.

We still believe that an approach such as the one we suggested or a similar model is necessary for CMS to achieve its goal of supporting innovation. The ESRD PPS is unlike other Medicare payment systems in two important ways. First, it is a single payment bundle. While there are hundreds of MS-DRGs or APCs, there is only one ESRD rate. Second, there is no annual recalibration of the ESRD PPS to account for the addition of new products or to recognize efficiencies because there is only one ESRD rate and nothing to balance the changes in that one rate against. Thus, applying only the transitional add-on policy provides only half a solution. The adjustment of the rate is also needed to promote the long-term availability of innovative products.

KCP acknowledges that CMS has to some degree recognized the fact that the bundled rate may not be sufficient for all new products. However, providing new money to the bundle only when a new drug or biological product is outside of the functional categories is too narrow of a policy. The functional categories as currently defined are so broad that they encompass nearly all of the categories of conditions for which dialysis patients seek treatment. These are also the areas in which there are the greatest gaps in treatment options, as evidenced by the fact that many of the products used today are valued (in terms of dollar amounts) so little. In some cases, clinicians do not even believe these products are effective for managing the conditions of patients. At a minimum, the policy CMS outlined for products outside of functional categories should be applied to all truly innovative products, even if they come within an existing functional category.

The limitations on TDAPA, which KCP discusses below and to which KCP suggests one modification, should be used as well to limit which products qualify for the evaluation to determine if new money should be added before the product is incorporated into the ESRD PPS. This amount should be tailored to provide the incremental difference between the existing amount in the bundle and the increased cost resulting from adding such a product. (See Section B for more details). In some cases, CMS might add the full cost of the drug, based on the data it obtains during the TDAPA period. In other cases, it may be appropriate to add some amount less than the full cost to account for dollars that may already be associated with the functional category in the bundle already.

Since its inception, KCP has fought to modernize federal policies to promote efficient, high-quality kidney care. We have raised concerns as the treatment options for patients living with other chronic diseases outpaced those available to dialysis patients. We have supported the efforts of our members to increase NIH funding for research in the areas of CKD and ESRD. We have called on the Congress and the Administration to recognize the gaps in kidney care and to create and expand education initiatives, such as the Kidney Disease Education benefit. Thus, when the President announced the Advancing American Kidney Health, KCP immediately

recognized the synergies between our ongoing work and the goals of the Administration. It is critical that the payment policies for the ESRD PPS support the Administration's goals. To that end, we ask that CMS in the final rule clarify that for CY 2020 and subsequent years it plans to evaluate truly innovative drugs and biologic products, regardless of their functional category status, as well as devices, and adjust the bundled rate as necessary to provide adequate payment that incentivizes the continued use of innovative products after the transitional period for the product ends.

B. KCP supports some of the proposed refinements to TDAPA, but continues to urge CMS to use it as a pathway to promoting innovation within the bundle after the transitional period expires.

KCP does not support CMS' proposals to condition TDAPA payments to facilities for a particular drug on the manufacturer's provision of ASP data. We agree that it is important for manufacturers to report ASP data, but cutting payments to facilities will not accomplish that goal. KCP recommends that CMS use other mechanisms already at its disposal to address the problem directly with the manufacturers that are not reporting. CMS could also consider using the Average Manufacturer Price (AMP) after a certain period of time.

KCP supports the exclusion of generic products from TDAPA, consistent with our previous comments and CMS' statements in the Proposed Rule. While we understand the desire to promote biosimilars, we believe the same rationale exists for excluding these products from the TDAPA payments as well. The money saved from excluding generics and biosimilars from TDAPA could be used to offset the cost of adjusting the ESRD PPS bundle when new drugs or biological products, including those defined by CMS to be in functional categories, are added to the bundle. We remain concerned, as noted above, that without assessing truly innovative products when they are added to the bundle that CMS will thwart its own stated goals of promoting innovation in the ESRD program.

In addition, KCP remains concerned that CMS has not revised the policy to base the TDAPA rate on ASP+6 percent, consistent with how other Medicare payment systems treat new drugs. As described below, we appreciate that CMS considered the hospital payment system when establishing the proposal for truly innovative devices, so it is unclear why the agency would not try to align the basis for the payment of new drugs and biological during a transitional period with the policies set forth in other payment systems. As we described in detail in our letter last year and as Table A demonstrates, there is very little money in the bundle for the majority of drugs or biological products. We believe it is a mistake, therefore, to assume that the bundled rate includes the administration costs associated with new products. If facilities purchase drugs at rates higher than the ASP, which at least half of the facilities do, and there is no adjustment for such administrative costs, it is difficult to see how TDAPA will inspire them to adopt innovative products. They simply will not be able to pay for such

products if the reimbursement is significantly below the cost of obtaining and administering the products.

KCP also supports CMS' decision to use NDA Classification Types for TDAPA eligibility, as proposed, with an important caveat that, if a product falls into an excluded NDA Type, but obtains FDA approval for its first ESRD-related indication, that product should be eligible for TDAPA. KCP also strongly encourages CMS and FDA to work together to: (i) provide greater transparency into the NDA Type decision; and (ii) develop a process for manufacturer involvement in that decision. We believe the approach proposed aligns with the intent of the criteria that KCP recommended CMS consider during the previous year's rulemaking to limit TDAPA eligibility. The funds that would no longer be expended under the Agency's original broader TDAPA policy could be used to offset the cost of adjusting the base rate to address the incremental cost of the TDAPA-qualified new drugs or biological products when they are added to the bundle.

KCP asks CMS to adopt KCP's recommended modification to the Agency's proposed TDAPA eligibility criteria, because without such modification, the utilization of the NDA Classification Types has the significant potential to exclude from TDAPA eligibility truly new and innovative drugs for ESRD patients. CMS recognizes in its discussion of the Type 10 NDA that a new ESRD indication for a previously approved non-ESRD drug advances the field and presents a new approach to provide care for ESRD patients. The reality, however, is that not all products for which a manufacturer obtains a new ESRD indication will be approved through a Type 10 NDA. For example, a product originally approved for a non-ESRD indication through an excluded NDA Type may have a first ESRD-specific indication added through an NDA supplement to that NDA, thus resulting in the new ESRD product being excluded from TDAPA eligibility. The innovation and investment by this manufacturer to obtain the new ESRD indication is no less than that of the manufacturer who submits a Type 10 NDA for a new indication, but the proposed criteria would exclude such a drug from TDAPA eligibility. By definition, a first ESRD-related indication denotes that the product has not been approved for this population previously and is consistent with the intent to limit TDAPA to truly innovative products for this patient population, regardless of the mechanics of the FDA approval.

We continue to believe that TDAPA should be applied only to truly innovative drugs and biological products. The proposed NDA Types create objective categories to identify new and existing products for TDAPA eligibility and eligibility for line extensions or other products that are sufficiently innovative to warrant additional funding. This approach provides certain and predictability to the process and will create the appropriate incentives for manufacturers to develop innovative products for the space, when coupled with the recommendations to add new dollars to the base rate when such products are added to the bundle.

Once the decision is made to limit TDAPA, CMS should align the drug designation policy with other Medicare payment system policies related to incorporating new drugs and biologic

products into a bundled payment system. This policy would mean that CMS collect two full years of claims data before folding the product into the ESRD PPS bundle and adjust the rate accordingly to account for the new costs, as well as an efficiencies that might be gained. As we noted in previous comment letters, CMS and the Congress have recognized that a two calendar year period is rarely sufficient to assess the utilization and cost of a new product. We are pleased that CMS has recognized that fact in the calcimimetic policy proposed in this rulemaking as well. Similar logic should apply to any new product that qualifies for TDAPA.

These incremental adjustments would ensure adequate funding for the long-term adoption of such products and is necessary because the ESRD PPS has no mechanism, unlike the hospital payment systems, to account for the additional incremental costs that may be associated with the addition of new products to the bundle.

C. Proposed transitional add-on for truly innovative devices and suggests some refinements

KCP appreciates that CMS has proposed the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES), which aligns in many ways with the recommendations that KCP made during the last rulemaking cycle. We support a transitional period for truly innovative devices. Similar to our recommendations for TDAPA, we recommend that CMS continue to apply TPNIES so that it has two full calendar years of data about the utilization and cost. Then, as with the drug designation policy, we ask that CMS adjust the base rate to include dollars for the incremental difference of the cost of the new device and what may be in the bundle already. We believe this comprehensive approach is the best way to align the TPNIES policy with the President's goal to incentive the adoption of new innovations in the ESRD program.

In addition, we ask that CMS work with KCP to propose in the next rulemaking a pathway for accounting for new capital equipment in the ESRD PPS. The inpatient hospital NTAP payment for new devices does not address capital equipment because those costs are incorporated in the base rates using other mechanisms linked to the cost reports. There is no similar mechanism for the ESRD PPS, so KCP asks that CMS propose in the FY 2021 proposed rule a mechanism that would adjust the base rate to account for the cost of innovative capital equipment as well. This policy is important because many innovative devices items, including some that the that the President has highlighted, would be capital equipment.

KCP also asks that CMS ensure that the pricing for the TPNIES is transparent and provide predictability and consistency in pricing. We would welcome the opportunity to work with CMS to create a transparent structure around the process the Medicare Administrative Contractors will use to set the list price.

Finally, we ask that CMS shift the application deadline to later in the year. We are concerned that the February 1 deadline may be difficult to meet, but the September deadline might not provide enough time for CMS to apply TPNIES in the next calendar year. We also ask that CMS provide a look-back period to January 1, 2019.

D. Calciumimetics

KCP supports extending the TDAPA for calciumimetics for a third year. As CMS has recognized, it is important that there is adequate information about utilization and practice patterns for new products before folding them into the ESRD PPS. We believe that having two full years of claims data is necessary to obtain the data needed to determine the appropriate adjustment to the base rate once the transitional period ends.

However, we are disappointed that CMS has proposed to reduce the basis for the calciumimetic TDAPA to ASP+0 percent. In terms of calciumimetics specifically, the ASP does not reflect the cost of many facilities who purchase products well above ASP. CMS has indicated in previous rules that the bundled rate does not include costs associated with oral drugs. At a minimum, this statement means that the cost of dispensing oral drugs is not included in the base rate. Other Medicare payment systems provide dispensing fees to recognize such costs. In addition, given the amount of dollars attributed to the functional categories other than anemia management, it is difficult to see how any dollars could be used to cover the administrative costs of calciumimetics or any other products. Therefore, we respectfully ask that CMS recognize that the negative Medicare margins, coupled with the fact that the bundle was created without incorporating the cost of administering oral drugs, and finalize ASP+6 percent as the basis for the calciumimetic TDAPA.

Additionally, we reiterate our request that before CMS automatically folds these drugs into the bundle, it consider how their limited utilization will impact the distribution of dollars that will be added. We reiterate our recommendation that CMS work with stakeholders to develop a mechanism that does not result in facilities that provide the drugs used by only a small percentage of dialysis patients do so at a significant loss, while facilities that do not provide these drugs receive additional payments because the amount added to the base rate is distributed evenly across all payments. We also ask that CMS outline in the final rule (with a comment period as well) the methodology and data it plans to use to value these drugs when they are added to the bundle. During the TDAPA period, we recommend that CMS work with the community to develop an approach that does not disincentivize their continued utilization once the TDAPA period ends.

II. KCP continues to suggest refinements to the ESRD PPS with regard to the case-mix and facility level adjusters and outlier policy.

A. ESRD PPS adjusters should be refined.

We reiterate our recommendations that CMS eliminate the co-morbid case-mix adjusters for pericarditis, gastrointestinal tract bleeding with hemorrhage, hereditary hemolytic or sickle cell anemia, and myelodysplastic syndrome, because the documentation of these conditions is burdensome and increases costs of facilities and the coinsurance obligations for patients, without providing sufficient benefit to justify their use. We have provided substantial clinical and analytical support for this recommendation in previous comment letters on the ESRD PPS proposed rules, which we incorporate by reference here. Eliminating these adjusters would allow the funds to be returned to the base rate and used to enhance the patient care overall.

In addition, we ask that CMS closely review the age, weight, low-volume, and rural adjusters. MedPAC has voiced concerns about each of these adjusters and the methodology used to create them. As currently defined, the age and weight adjusters add substantial provider burden without actually achieving the goal of case-mix adjusters, which is to eliminate disincentives to provide care to more expensive patients by increasing rates for those patients with characteristics that predict higher costs.

During the December 8, 2018, ESRD PPS Technical Expert Panel (TEP) meeting convened by CMS' contractor, the panelists aligned around these concerns. Even when pressed to try to identify additional new adjusters, the vast majority indicated that very few adjusters are really necessary for the ESRD population. They reiterated concerns about the comorbid case-mix adjusters, with most panelists calling for their elimination. They also articulated concerns about the age, weight, and facility-level adjusters, highlighting the need to revise them. Given these concerns, it is time for CMS to fix these long-standing problems and revise the case-mix and facility-level adjusters.

MedPAC has also expressed concern about the overlapping nature of the low-volume and rural adjusters in its most recent Commission meetings. In the April 2019 meeting, the staff presented an "illustrative example" of a single low-volume and isolated (LVI) facility adjuster that would better target payments. KCP conceptually supports such an approach, as we have indicated in our previous comment letters on the ESRD PPS.

The continued application of these policy results in the actual dollars CMS pays out for ESRD care to be significantly less than what the Congress had indicated it should be. While sequestration continues to be a driving source of underpayments, the underpayment amount attributable to other factors, which are due to a mismatch among adjusters frequencies assumed by the standardization factor compared to actual payment increased substantially in

2018, remains high. The Moran Company estimates that taken together, the total underpayment for the PPS per treatment in 2018 was \$11.11. The underpayment due to the outlier pool was \$1.54 per treatment. Sequestration accounted for \$4.45 per treatment, with the QIP taking out 25 cents per treatment. The remainder of the underpayment appears to be due to the fact that CMS has incorporated the calcimimetics into the outlier pool calculation. As described below, KCP strongly objects to this inclusion. Given the negative margins, each dollar that comes out of the program reduced the funding available to support patient care and innovation.

In sum, KCP urges CMS to act immediately upon the years of analyses and recommendations provided by KCP, our members, and MedPAC to refine the ESRD PPS adjusters. Taking this step would also better direct reimbursement to enhance patient care and outcomes.

B. The outlier policy should be revised.

KCP is deeply concerned that CMS has decided in this Proposed Rule to include the TDAPA costs for calcimimetics in the outlier calculation, even though the drugs are not eligible for an outlier payment. While the statute requires CMS to include as part of the single payment amount for the ESRD PPS “a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care,”⁶ it does not provide specifics as to how the outlier pool is determined or paid out. We understand that CMS believes that TDAPA is not outside of the ESRD PPS single payment amount, but remain concerned that the calcimimetics should be included in the outlier pool. Yet, there is no ability to recover the dollars and they are permanently removed from the program. The Congress established an outlier pool so that facilities treating extraordinarily costly patient are not disincentivized from doing so. The interpretation of the statute that suggest an add-on be incorporated into the outlier calculation is inconsistent with this intent.

III. KCP recommendations on other CMS proposals

A. Wage index

KCP generally continues to support the methodology for determining the wage indices and the continued application of the wage index floor. However, we ask that CMS consider how the current policy could be modified to adjust wage index values to take account of laws requiring wage increases. Under the current methodology, there can be a several year lag with the wage index recognizing these changes.

⁶42 U.S.C. § 1395rr(b)(14)(D)(ii).

B. EMP policy

KCP supports updating the PPS by eliminating the application of the ESA Monitoring Policy (EMP) to the outlier payment. As CMS articulates in the Proposed Rule, given that ESAs have been incorporated into the ESRD PPS, the underlying rationale that supported the EMP no longer exists. Yet, given the importance of monitoring anemia in patients, we encourage the Center for Medicare to continue collecting patient hemoglobin levels despite the changes in the EMP.

C. Price Proxies

KCP urges CMS in the coming year to work with the industry to find a better 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. The current category references “vitamins,” in a way that does not appropriately capture the price of drugs that fall within this category. Currently, 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.

D. Productivity Factor

We also reiterate our concern that the overall negative Medicare margins that the majority of dialysis facilities experience argues against the idea that productivity can be improved year over year. As noted in the August 10, 2018, letter, the Medicare rates are inadequate to cover the cost of providing services. MedPAC in its most recent Report to the Congress indicates that the aggregate Medicare margin was –1.1 percent in 2017, and the 2019

Medicare margin is projected at –0.4 percent. This estimate is high in our view because it does not account for actual revenue reductions, such as the Network Fee that reduces each payment by \$0.50 and the substantial amount of unrecovered bad debt. If just these two amounts were taken into account, the average margin would be negative. Using CMS data, The Moran Company estimates that 55 percent of facilities have negative margins – their revenues do not cover the cost of providing services already.

While the ESRD PPS may have been implemented only in 2011, the labor and other basic items and services used in dialysis facilities prior to that date were already bundled in what was known as the composite rate. The composite rate drove efficiencies as well. Under the ESRD PPS, facilities are being asked to do more each year as the number of ESRD-related quality programs and measures used in them expand, the regulatory and documentation burdens increase, and the labor and staffing requirements also increase. The costs of labor, in particular, are increasing dramatically. For example, facilities are subject to staffing ratios and labor hours per treatment that cannot be reduced without placing quality patient care at risk. As we have noted as well, the cost reports do not reflect these requirements and do not align with the actual experience of dialysis facilities. The Medicare Trustee Report recognizes that for the productivity factor to achieve its goals, “health care providers would have to realize productivity improvements at a faster rate than experienced historically.” If this reality is not achieved – which seems unlikely, especially in the dialysis sector – “the availability and quality of health care received by Medicare beneficiaries would, under current law, fall over time compared to that received by those with private health insurance.” Despite the statutory restrictions, we encourage CMS to work with the kidney care community to find a more appropriate adjustment and potentially to encourage the Congress to eliminate this requirement based on the economic instability of the industry.

E. Network Fee

KCP encourages CMS to allow facilities to include the 50 cents per treatment Network fee on the cost reports. For example, in 2016 there were 38,343,333 dialysis treatments administered. This means that CMS and other policy-makers were not taking into account nearly \$20 million of cost incurred by dialysis facilities. That number has only increased over time.

Historically, there may have been concerns about whether the statute permits such recognition. A closer review of the statute and legislative history, however, shows that the Congress was silent on the question. The Congress established the Network Fee as part of the Omnibus Budget Reconciliation Act (OBRA) of 1986.⁷ The statute includes no express language that states whether or not the fee should be incorporated into the cost report.

⁷Social Security Act (SSA) § 1395rr(b)(7), as added by section 9335(j)(1) of OBRA '96.

While the legislative history provides a clear description of the rationale behind the changes made to the ESRD Networks in the OBRA '96, it is equally silent as to how CMS should treat these fees on the cost reports.⁸ Given the text and the legislative history's silence on this point, KCP believes CMS has sufficient authority to allow facilities to include the Network Fee in their 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 2020.

F. Renal Dialysis Humanitarian Use Devices (HUD)

KCP appreciates that CMS is seeking comments on creating a HUD policy for the ESRD program. As the Proposed Rule explains, a "HUD is a 'medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year,' under FDA regulations." Generally speaking, KCP supports the concept. However, in the experience of our members, the more critically important need is for humanitarian relief when there are natural disasters. Hurricane Dorian has brought to mind the ongoing struggle that patients, clinicians, and facilities face in trying to obtain basic supplies and equipment to care for dialysis patients who find themselves in the path of such storms. Therefore, we ask that CMS work with KCP and its members to develop appropriate humanitarian policies to protect access to products and suppliers during such events.

G. AKI policies

KCP supports the proposed AKI payment rate for CY 2020.

In the CY 2017 final rule, CMS announced that it would be developing a formal monitoring program, but the specifics have yet to be published. We would also find it helpful

⁸ H.R. Rep. No. 727, "Omnibus Budget Reconciliation Act of 1986," 99th Cong., 2d Sess. 78 (1986).

to understand how CMS is monitoring the AKI benefit. Additionally, we reiterate our interest in maintaining a dialogue as part of this monitoring program to ensure that the payments for AKI patients are adequate. As we have noted in previous letters and consistent with the work of the Renal Physicians Association, it may be necessary to establish "AKI adjustment" to the payment rate to address the differences in the services provided to AKI patients from those provided to ESRD patients. We would welcome the opportunity to work with CMS on these issues.

IV. Conclusion

KCP appreciates the opportunity to provide comments on the Proposed Rule. Kathy Lester, our counsel in Washington, will be in touch to schedule a meeting. However, please feel free to contact her at any time if you have questions about our comments or would like to discuss any of them in further details. She can be reached at klester@lesterhealthlaw.com or 202-534-1773. Thank you again for considering our recommendations.

Sincerely,

A handwritten signature in black ink, appearing to read "Allen Nissenson".

Allen Nissenson
Chairman
Kidney Care Partners

cc: Demetrios Kouzoukas, Principal Deputy Administrator
Ing-Jye Cheng, Acting Director Chronic Care Policy Group
Abigail Ryan, Director, Division of Chronic Care Management

Appendix A: Kidney Care Partner Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
Ardelyx
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
AstraZeneca
Atlantic Dialysis
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
Dialysis Clinics, Inc.
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Renal Administrators Association
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care