KIDNEY CARE PARTNERS

September 3, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS–1732–P: "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program"

Dear Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the "End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program" (Proposed Rule). This letter outlines our recommendations about the proposals related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). Our comments on the Quality Incentive Program were shared in a separate letter.

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 continues to support the Administration's Advancing American Kidney Health initiative. When KCP members came together nearly 20 years ago, we sought to increase awareness among federal policy makers about the need for innovation and expanded treatment options. We continue to fight for policies to prevent kidney disease, increase patient choice, expand access to transplant, and support high-quality dialysis care. KCP worked closely with federal policy makers in the late 2000s to create the ESRD PPS and the first Medicare value-based purchasing program (the ESRD QIP).

Today, the kidney care community faces new challenges, especially when it comes to the substantial role that the federal government plays in the delivery of kidney care. While some patients under federal law have the right to retain their commercial insurance coverage after their diagnosis of ESRD, the vast majority of patients – nearly 395,000

according to the Medicare Payment Advisory Commission[1] – rely upon Medicare for their health care coverage. In essence, the Medicare ESRD benefit is becoming a single payer system, making it more important than ever that the payment system is responsive to patient need and clinical advances.

In sum:

- KCP generally supports CMS's proposal to add new money to the ESRD PPS base rate for calcimimetics and recommends that CMS modify the methodology to use a more appropriate utilization and price.

- KCP recommends that CMS work with KCP to address the addition of high-cost products to the outlier pool to ensure that the outlier payment is available for multiple types of high-cost patients.

- KCP supports the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and seeks modifications to the proposed changes to the policy before they are finalized.

- KCP asks CMS to use its existing authority to modify the base rate when a new drug or biological is added to the ESRD PPS, even when the product is found to be within a functional category, and to allow for the TDAPA period to be two to three years.

- KCP generally supports the ESRD PPS Update for 2021, but recommends that CMS address the unresolved problems with the case-mix and facility-level adjusters, as well as modify the price proxy for certain drugs and amend the cost reports to capture the Network Fee.

- 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 patient modality choices and suggest specific policy changes within CMS's current authority to support expanding the number of patients who select home dialysis modalities.

When implemented of the ESRD PPS was a great success. However, the system has limitations that now create barriers to the development and adoption of innovative products and services. These products and services promise to improve patient care and quality of life, yet are disincentivized by the current program. Additionally, the consistently negative margins calculated by MedPAC demonstrate the precarious nature of the program.

[1]MedPAC, *Report to the Congress* 169 (March 2020).

The most recent report shows positive margins only with temporary add-on amounts included in the calculation. Those add-ons end in 2021.

In this letter, we highlight some of the aspects of the program that the Administration could address through regulation, such as creating a stable pathway for long-term adoption of innovative products by adding new money to the base rate, as described in more detail in Sections III and IV, as well as addressing concerns with the adjusters, outlier policy, and other issues set forth in Section V. There are other issues that we recognize require Congressional engagement and modification to the authorizing statute. We encourage CMS to join us in these efforts to improve the ESRD PPS, which not only is the core of the traditional Medicare program, but also has been the basis for the various payment model innovation projects that KCP members have partnered with CMS in pursuing over the years. It is important to improve the PPS to ensure the most innovative and high-quality care for this vulnerable population. The federal government entered into a successful covenant to provide comprehensive health care coverage for these patients which has, since its inception, extended the lives of countless Americans. KCP seeks to partner with CMS as it fulfills this commitment.

The following principles outline the direction we believe the program needs to move toward. The ESRD PPS should:

- Reflect the cost of providing dialysis care to patients;
- Allow for the adoption of innovative products and services;
- Meet unique clinical needs of each patient;
- Promote coordination of care among patients' providers, including hospitals and transplant centers;
- Provide patient modality choice;
- Support continued quality improvement; and
- Support transplant.

During the coming months, KCP would like to work closely with CMS and the Congress to expand upon these principles and modernize the ESRD PPS as well as other policies, including those related to the ESRD quality programs, fraud and abuse laws, organ transplant waitlist requirements and policies, and innovative payment models.

I. KCP generally supports CMS's proposal to add new money to the ESRD PPS base rate for calcimimetics and recommends that CMS modify the methodology to use appropriate utilization and price data.

KCP appreciates that CMS provided a three-year transitional add-on period under TDAPA for calcimimetics before adding them to the ESRD PPS bundle. As the preamble indicates, this time was important to collect data related to the utilization of the drug, because it allowed CMS to have two full calendar years of claims data to assist in determining the dollars that will be added to the base rate. We also generally support the

proposed methodology to use the utilization multiplied by price then divided by the number of treatments to determine the per treatment rate that will be added to the base rate, and recommend two modifications related to the data used to determine utilization and price with regard to the proposed methodology. KCP does not support the alternative methodology that would use CYs 2018 and 2019 expenditures divided by the total number of paid hemodialysis (HD)-equivalent treatments furnished during the same period. We agree with CMS that this alternative approach does not reflect the more current market dynamics.

A. KCP recommends that CMS use the most recent publicly available 12 month utilization data to establish the utilization rate; CMS should not use claims data from 2018.

KCP recommends that CMS not use the proposed CYs 2018 and 2019 data for establishing the utilization of the calcimimetics, but instead use the most recent publicly available 12 months of claims data. As noted below, The Moran Company analysis demonstrates that the data from 2018 are not reflective of the utilization of these products. Using the most recent 12 months of data also aligns with CMS's proposal to use the most recently available ASP data for establishing price.

While having two full calendar years of data (which requires having three years of TDAPA to address lags in data) is important to understand the utilization trends for innovative products, our recommendation on the length of the TDAPA period does not mean that CMS should have to use two full calendar years of data for establishing the utilization. CMS should rely upon data that reflects the current utilization. This approach would be consistent with other Medicare payment systems, such as the inpatient and hospital outpatient prospective payment systems, that traditionally rely upon the most recent year of available claims data as well.

Based on an analysis performed by The Moran Company, 2018 is not stable enough to include in the utilization calculation. For example, 2018 data show substantially lower utilization of calcimimetics overall, which we believe is due to the TDAPA implementation challenges as well as, in part, to patients having a supply of oral calcimimetic drugs during Q1 from the 2017 Part D supply; this would have reduced utilization under Part B artificially, while also slowing the adoption of the IV product.

Table 1: Calcimimetic Utilization 2018-19

Quarter	Total Hemo-Equivalent Treatment Units	Total Hemo-Equivalent Treatment Units Associated With Calcimimetic Use	Oral Calcimimetic Units	Change in Oral Calcimimetic Use	IV Calcimimetic Units	Change in IV Calcimimetic Use
2017 Average Quarterly Part D Use			267,015,140		-	
2018 Q1	11,352,833	2,638,997	215,598,987	-19%	7,793,307	
2018 Q2	11,512,188	3,017,936	268,013,568	24%	19,479,469	150%
2018 Q3	11,615,268	3,069,239	260,355,524	-3%	28,406,791	46%
2018 Q4	11,691,983	3,132,088	241,933,003	-7%	37,674,170	33%
2019 Q1	11,100,094	3,039,769	217,267,952	-10%	43,300,304	15%
2019 Q2	11,262,306	3,131,806	214,892,251	-1%	51,991,461	20%
2019 Q3	11,608,533	3,300,102	207,541,189	-3%	58,318,787	12%
2019 Q4	11,493,279	3,264,374	207,302,392	0%	61,346,494	5%

Note: The 2017 Average Quarterly Part D Use units for oral calcimimetics does not necessarily include all Medicare ESRD patients, given that some patients have drug coverage outside of Part D or may not have coverage.

The IV calcimimetic became available in 2018 and its utilization increased each quarter during the TDAPA period. The chart demonstrates continuous growth quarter over quarter, which one would expect to see with the adoption of a new product as physician and facilities integrate it into clinical practice; this supports the importance of using the most recent publicly available 12 months of data. The share of all treatments associated with calcimimetic use rose from 26.2 percent to 28.4 percent from Q2 2018 to Q4 2019. These results show that it is important to have a sufficient period of time to allow physicians to understand a new product and determine which patients may benefit from its administration. When determining the amount that is added to the base rate, it is important to use the best available data and avoid using early data that does not reflect the adoption of the product accurately.

There may be times when it is appropriate to use partial-year data that includes data over two different calendar years. For example, it might be appropriate to include Q1 2020 claims data in these twelve months of data, if the 2020 data is available with a run-out period that is equivalent to the run-out period associated with claims data typically used in setting the annual updates to the base rate (i.e., 90 days). If CMS were to use these data, they should be publicly available prior to allow for stakeholders to analyze the data as well.

If CMS were to adopt this recommendation, we assume that the final rule would use the same time frame (the most recent publicly available 12 months of claims data) to determine the total number of HD-equivalent dialysis treatments paid to determine the per treatment amount.

Again, KCP appreciates that CMS provided TDAPA for three years for calcimimetics to allow it to have claims data that more accurately reflects the physician-prescribed utilization of the products. As The Moran Company analysis demonstrates, the most recent

12 months of publicly available claims data provides a more accurate picture of the utilization of the products.

B. KCP supports the use of the most recent quarter of Average Sales Price (ASP), but again recommends that CMS return to ASP+6 percent.

KCP agrees that it is appropriate to use the values from the most recently available calendar quarter data for determining the increase in the base rate to account for adding calcimimetics to the bundle. However, we continue to remain concerned that using ASP+0 percent does not accurately reflect the cost providers incur when purchasing and administering these drugs. By using ASP+0 percent, the amount added to the base rate will be artificially low.

Other Medicare payment systems, such as the hospital payment systems, rely upon ASP+6 percent treat new drugs and biologicals. As we have noted in previous comment letters, the bundled rate does not include the administration costs associated with new products. Because ASP represents an average price, some of the facilities purchase products at rates higher than ASP. Thus, using ASP+0 percent to set the rate at a level lower than their costs does not create the incentive CMS intends the policy to promote. Therefore, we agree that CMS use the most recent quarter of ASP, but that it should be set at ASP+6 percent.

C. KCP asks CMS to address unresolved billing guidance issues related to calcimimetics.

With calcimimetics moving into the ESRD bundle for CY 2021, it is important that CMS address an issue that arose with the publication of Change Request 10065. Under this guidance, only the amount of the oral calcimimetic that a facility anticipates a patient will take during the calendar month may be reported on that month's ESRD claim. CMS requires the facility to report the difference between the actual number of units taken and expected number of units on the next month's claim. However, as our members have noted during the transitional TDAPA period, there may not always be a claim for a patient during the following month. This means that some drug has been given to the patient is never billed as a result of the patient not being treated for the full duration of the prescription. This gap creates a non-billable losses, which is in addition to prescription changes that are not billed and unrecoverable patient copayment obligations that cannot be collected and are not subject to Medicare bad debt recovery.

KCP is concerned that if this policy remains unchanged, then there will be a gap in the TDAPA between the December 2020 and January 2021 claims. To resolve this problem, we ask that CMS provide a billing exception to allow facilities to report the total amount of the oral drug that is dispensed for December 2020.

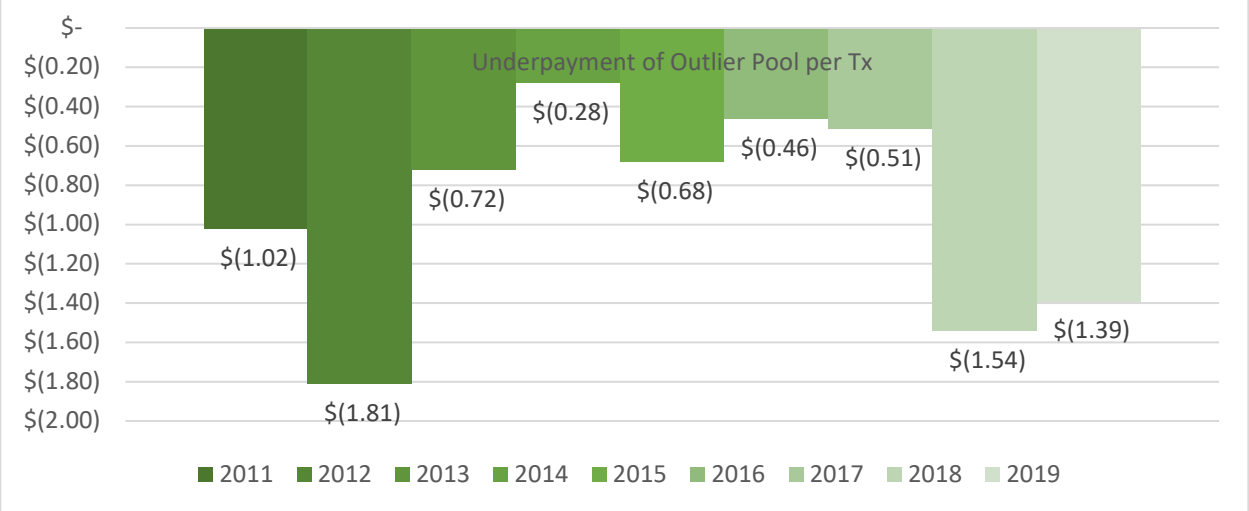
In sum, we appreciate CMS's approach to adding calcimimetics to the base rate and urge CMS to use the most recent publicly available 12-month claims data, instead of the proposed 2018 and 2019 claims data, to determine the utilization for the calcimimetics. This work underscores the importance of having policies to address the long-term sustainability of the program when adding new products, especially innovative products, in the bundle.

II. KCP recommends that CMS work with KCP to address the addition of high-cost products to the outlier pool to ensure that the outlier payment is available for multiple types of high-cost patients.

Since the beginning of the ESRD PPS, the outlier pool has not paid out the full amount withheld each year. As described below, now that calcimimetics qualify for outlier payments, there will be a significant shift of the patients who qualify for outlier payments. It is important to address both the longstanding issue that outlier thresholds are consistently set too high, resulting in underpayment of the outlier pool, and to address the emerging issue of significant shifts in outlier eligibility when new therapies become eligible for outlier reimbursement to protect access to such therapies by ensuring that outlier payment is available for higher-cost cases.

As CMS has explained each year, the dollars withheld for the pool have never been paid out in a manner that reaches the 1.0 percent withhold. This has meant that dollars intended to reimburse the costs associated with more expensive patients have not been distributed and are lost to the system.

Figure 1: Underpayment of the Outlier Pool on a Per Treatment Basis 2011-2019



Source: The Moran Company analyzing CMS data.

Historically, KCP and others in the kidney care community have recommended that CMS reduce the outlier pool withhold to less than 1 percent and, in some years, even to zero. We continue to believe this approach would be consistent with the intent of the Congress. When it authorized the pool, the Congress did not set a minimum percentage. We continue to reiterate this recommendation.

With the inclusion of the calcimimetics in the ERSD PPS, facilities will face new challenges with regard to the outlier pool. First, CMS is projecting substantial increases to outlier thresholds, both the FDL and MAP amounts. As described below, this could further exacerbate the longstanding issue of the outlier pool being underpaid. In addition, the proposed substantially higher thresholds will require greater losses before the outlier pool will be triggered. Second, The Moran Company has found that the cases qualifying for outlier payment will shift. The proportion of the outlier payments associated with patients receiving IV calcimimetics would increase substantially. They also found that many patients whose treatments historically qualified for outlier payments would no longer qualify under CMS's proposal due to the significant increase in the outlier threshold.

Under the CMS proposal, the per treatment amount at which the outlier payment begins in order to receive an outlier payment will increase 123 percent compared to the threshold for 2020, due to the eligibility of calcimimetics for outlier payment. The Moran Company found that while IV calcimimetics appeared on only 7.8 percent of claims in 2019, these products would account for 67.3 percent of outlier-eligible claims under the Proposed Rule. Claims without calcimimetics made up 73 percent of all claims in 2019, but would make up 23.7 percent of all outlier-eligible claims under the Proposed Rule. Claims using only oral calcimimetics make up 19.2 percent of all claims, and would be associated with 9 percent of outlier-eligible claims.[2]

Analysis of the facility level impacts from the Proposed Rule projections tell a similar story:

- The 30 percent of all facilities that did not use IV calcimimetics in 2019 are projected by CMS to see a 70 percent decrease in outlier payments under the proposal.

- The top 10 percent of facilities ranked by IV calcimimetic use would experience an increase of 172 percent in their outlier payments.

Based on this analysis, The Moran Company concluded that:

The post-TDAPA inclusion of calcimimetics in the pool of outlier eligible services drove the substantial increase in the amount per treatment facilities

[2]This analysis does not include pediatric claims, because of the lower utilization of calcimimetics in pediatric patients.

must lose before becoming eligible for outlier payments. These outlier payments will be disproportionately directed to cases using IV calcimimetics.

The Moran Company also notes that if there is any decrease in utilization or the price of calcimimetics in 2021, the outlier pool, as proposed, would result in a substantial amount of dollars being taken out of the system in that year alone—perhaps as much as $60 million. For this reason, we urge CMS to lower the thresholds for outlier payment for 2021. Given that CMS has never paid the target amount in the ESRD PPS and in the most recent year only paid half of the target amount, CMS should not increase the thresholds as significantly as proposed and should consider much lower thresholds for CY 2021 than were proposed.

Yet, this dynamic shift in outlier eligibility will not be unique to calcimimetics. Any new product that qualifies for the outlier pool and has a significant cost associated with it will lead to higher threshold amounts. This 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, which we saw occur with ESAs historically.

There are likely different ways to address this issue. 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. One option we could explore is to reserve a portion of the pool that would be in proportion to the share of the new services, in this case calcimimetics, compared to the current spending on all other outlier-eligible services in the ESRD PPS. Under this type of policy, CMS could establish a MAP and fixed-loss amount for each sub-pool. The total value of the pool could remain at 1 percent (or less as noted above) of the ESRD PPS. CMS would recalculate the size of the sub-pool based on the most recently available claims data. Overtime, CMS would evaluate whether additional functional categories would merit the creation of additional sub-pools. In addition to allowing the outlier pool address higher-costs patients outside of the calcimimetic costs, the distributed nature of the sub-pools would decrease the risk of dollars being removed from the payment system unintentionally.

KCP would like to work with CMS to refine the outlier pool to make sure that it addresses the needs of high-costs patients.

III. KCP supports the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) and seeks modifications to the proposed changes to the policy before they are finalized.

KCP supports the Administration's efforts to spur innovation in the area of kidney care. The ESRD PPS bundle has deterred innovators from engaging in kidney care because

the payment system does not account for the cost of developing and adopting product options for patients. TDAPA and TPNIES are important steps toward addressing this problem. 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 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. We also ask that CMS make sure that CMS fund the MA plan for significant expenditures in accordance with regulation, consistent with current policy that requires an increase in funding when a new product exceeds the threshold of current payments.[3] It is important that the MA plans are ready to implement these changes at the same time the TPNIES begins in the ESRD PPS.

KCP supports the proposals to change the current definition of "new" to give entities wishing to apply for the TPNIES three years beginning on the date of FDA marketing authorization in which to submit their applications.[4] We also support the proposal to align TPNIES with the new biannual Coding Cycle 2 as specified in the HCPCS Level II coding guidance deadlines.[5] KCP also agrees with the proposed definitions for "capital-related assets,"[6] "home dialysis machine,"[7] "particular calendar year,"[8] "depreciation," "straight-line depreciation method," and "useful life."[9] However, we are concerned about the proposal to expand TPNIES to only one type of product and that there is no long-term sustainable pathway for truly innovative devices when the base rate does not contain a sufficient amount of dollars.

Removing barriers that make it difficult for patients to choose home dialysis modalities is an important goal, and one that KCP shares with the Administration. Through the years, KCP has supported legislation to eliminate barriers in the Medicare payments systems, such as reforming differential payments that had dis-incentivized home dialysis in the Physician Fee Schedule. We also have promoted reviews by governmental advisory bodies, including the Governmental Accountability Office (GAO), which issued a report entitled "End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis" in 2015,[10] based on legislation KCP developed with kidney-care champions in the Congress. While the percentage of dialysis patients who receive home dialysis has been rising for more than 10 years, we agree that more can and should be done to recognize and, where appropriate, ameliorate obstacles that patients who want to receive home dialysis face. These obstacles include having: an adequate

[3] 42 C.F.R. § 422.109
[4] *See*, *Fed. Reg.* at 42142.
[5] *See id.* at 42143
[6] *Id.* at 42147
[7] *Id.*
[8] *Id.*
[9] *See id.*
[10] GAO, "End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis" (October 2015).

home infrastructure to allow for home dialysis; a care partner(s) willing to assist the patient with home dialysis; better education for physicians, as well as patients and patients' care partners; and earlier detection of kidney disease and recognition of the need to educate patients about their treatment options earlier to avoid "crashing" into dialysis. In section Y, we offer specific recommendations to address these barriers and to increase the adoption of home dialysis by patients living with kidney failure. It is not clear, however, that singling out home dialysis machines only for a capital-related asset for TPNIES would significantly change the equation.

Fostering innovation in kidney care generally is also a central goal of the Administration's "Advancing American Kidney Health." 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. We support structuring TPNIES to help bring innovative products to all kidney care patients.

We appreciate that CMS is refining TPNIES and considering ways to include some capital-related assets, but we think it is important that the final rule recognize the option for other capital-related assets to qualify for TPNIES potentially in the future. KCP asks that CMS gather additional information about the Home Dialysis Machines when Used in the Home for a Single Patient TPNIES, as well as about all types of capital-related assets, and construct a policy that supports more than a narrow type of product. While we have sought to provide initial comments, this policy is complex and it would be helpful to have additional time to consider the proposals and alternatives. We support the Agency's note indicating that it will be seeking additional information about how ESRD facilities obtain their capital-related assets that have multi-patient usage. KCP suggests seeking additional comments on both of these policy areas through a request for information, as well as convening a technical expert panel(s).

If CMS were to move forward with the proposed TPNIES for Home Dialysis Machines when Used in the Home for a Single Patient, KCP generally supports the proposed methodology for establishing the TPNIES amount that relies upon the annual allowance and pre-adjusted per treatment amount. We also encourage CMS to work closely with KCP to provide guidance to ensure the appropriate implementation of this methodology and payment policy.

KCP does not support the alternative methodology CMS outlines for the proposed TPNIES for Home Dialysis Machines when Used in the Home for a Single Patient that "would offset the pre-adjusted per treatment amount by a value that would reflect the amount already included in the ESRD PPS base rate."[11] The purpose of a transitional pass-through payment is to incentivize the adoption of innovative products. Its purpose is not to reimburse providers dollar for dollar for their costs. The government assumes the risk

[11] *Id.* at 42151.

during the short transitional period, while providers take on that risk after the transitional period ends. This is true of the inpatient and outpatient hospital payment systems, as well as TPNIES. The "offset" concept is in contrast to the underpinning of this policy. According to The Moran Company, the proposed methodology, with perfect adherence and patient health, would result in a maximum TPNIES payment of 26 percent of the cost of the device paid over two years. We also ask for clarification whether TPNIES will follow the device. We believe it should be linked to the product itself. For example, if TPNIES is limited to the first patient that uses a specific product, then when patients discontinue home dialysis, are hospitalized, or die before the TPNIES period ends, the payment amount would be less. The Moran Company found that if the proposed offset were implemented, payment under the example provided by CMS would be reduced from $6,500 to $3,620 or only 14.4 percent of the cost of the machine. 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. Given that the 26 percent amount may not be sufficient to drive the innovation CMS seeks to promote, further limiting it as the offset proposal would only further reduce the likelihood of adoption.

Finally, KCP continues to ask that CMS reconsider the decisions to limit TPNIES to only two years and its conclusion not to adjust the base rate incrementally when a truly innovative device is added to the bundle. The experience with calcimimetics shows that having a three-year transitional period is important to allow for CMS to have the data needed to assess whether the base rate should be adjusted. As MedPAC has recognized year over year, the ESRD PPS base rate does not cover the cost of providing services to patients. The transitional add-ons provide an increase, but do not provide a long-term solution to the problem. Thus, as we indicated in our comments on TDAPA, it is appropriate for CMS to adjust the base rate to account for the addition of a new product added to the bundle once the TPNIES period ends.

In sum, we appreciate the efforts CMS has undertaken to incentivize the adoption of truly innovative devices. We hope to work closely with CMS during the comment period and in future years to make sure that the benefits of the transitional payment are not eliminated once the products are added to the bundle permanently.

IV. KCP asks CMS to use its existing authority to modify the base rate when a new drug or biological is added to the ESRD PPS even when the product is found to be within a functional category and to allow for the TDAPA period to be two to three years.

KCP continues to support the work CMS has done to remove barriers to adopting innovative products and services for kidney care. The Transitional Drug Add-on Payment Adjustment (TDAPA) has been a positive step toward removing the barriers created by the ESRD PPS. The Proposed Rule restates the current policy that CMS will not adjust the base rate when new innovative drugs and biologicals that would be within existing ESRD functional categories are added into the bundle. We understand that there may be

concerns about the legal authority CMS has to modify the base rate when new functional category products are added to the bundle. We thought it could be helpful for KCP to take the opportunity provided by this public commenting period to provide our assessment of that authority, which supports the request to adjust the base rate, when appropriate.

In rulemaking, CMS states that it has created TDAPA as a policy to place the risk of incurring the cost of new, innovative products with the government for a short-period of time, instead of it resting with providers. On its own, TDAPA helps with those initial years, but does not provide a sustainable pathway for adopting innovative products long-term. To be effective, the TDAPA should be coupled with a policy related to the base rate to achieve that goal. For calcimimetics and new drugs not in functional categories, CMS has established a policy to adjust the base rate once the TDAPA period ends. For functional category drugs, KCP recommends that CMS adjust the base rate incrementally to address the cost of these new drugs or biological products when they are added to the bundle after the TDAPA period ends.

We believe the statute provides CMS with the authority to adopt this policy. The authorizing statute states that the ESRD PPS "may include such other payment adjustments as the Secretary determines appropriate."[12] CMS cited this authority when it established the TDAPA policy and decision to add dollars to the base rate for calcimimetics and drugs/biologicals not within existing functional categories.[13] While there are examples of other types of adjusters outlined in the statute, the permission is permissive and not limited to these examples. Adjustments do not have to be case-mix or facility-level adjustments. Nothing in this section requires that the adjustments be budget neutral or otherwise limited.[14] In fact, the statute specifically established a budget neutrality requirement when adopting the transitional phase-in of the ESRD PPS, but only for the years of the phase-in:

> The Secretary shall make an adjustment to the payments under this paragraph for years during which the phase-in under clause (i) is applicable so that the estimated total amount of payments under this paragraph, including payments under this subparagraph, shall equal the estimated total amount of payments that would otherwise occur under this paragraph without such phase-in.[15]

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[12] 42 U.S.C. § 1395rr(b)(14).
[13] CMS, Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule 80 *Fed. Reg.* 68968, 69023 (November 6, 2015).
[14] *Cf.,* The inpatient PPS statutory authority requires that certain adjustments and updates be budget neutral. For example, 42 U.S.C. § 1886ww(d)(3)(E) states: "Any adjustments or updates made under this subparagraph for a fiscal year (beginning with fiscal year 1991) shall be made in a manner that assures that the aggregate payments under this subsection in the fiscal year are not greater or less than those that would have been made in the year without such adjustment." There is no similar language in the ESRD PPS.
[15] 42 U.S.C. § 1395rr(b)(14)(E)(iii).

If the Congress had intended payments to be budget neutral on an ongoing and permanent basis, it would not have limited the budget neutrality requirement to the phase-in years and would have instead included language similar to the acute inpatient hospital PPS.

Some might counter that the more specific language of the provision related to the ESRD PPS annual update mechanisms suggests that the Congress did not intend for permanent adjustments beyond the update mechanism, but that conclusion does not seem reasonable. The language that those who oppose an update would mostly likely point to is the phrase "the Secretary shall annually increase payment amounts established under this paragraph by an ESRD market basket percentage increase factor for a bundled payment system for renal dialysis services that reflects changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services." [16] Clearly, this language is very specific, but it does not eliminate the authority to establish "other adjustments" as the preceding paragraph indicates. And, while the annual update provision speaks in terms of an annual increase based on the ESRD market basket to the base rate,[17] it is a mandatory adjustment. The mandatory nature of the adjustment results in a construction that differs from the construction that is used for the permissive nature of the adjustments in the preceding paragraph.

Thus, it seems appropriate to conclude that: the Congress would allow CMS to establish additional adjustments beyond those enumerated in the statute; these adjustments do not have to be budget neutral; and the adjustments could be incorporated into the ESRD PPS base rate on a permanent basis.

The language authorizing the drug designation policy also provides CMS with discretionary authority to add new money to the base rate. In the Protecting Access to Medicare Act of 2014 (PAMA), the Congress required CMS to "establish a process for—(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under such system."[18] This language does not prohibit CMS from adding new money to the base rate as part of its process, which is evidenced from the fact that the current policy for calcimimetics and drugs that are not within existing functional categories can receive new money when they come into the ESRD bundle. The creation of the functional categories is a regulatory one and is not mandated by statute. The Congress knew of these categories when it established the authority. It did not differentiate in the text between drugs within these regulatory categories and those outside of it. Nor did it apply a budget neutrality requirement. Therefore, just as CMS has relied upon this provision as its authority to add new money to the ESRD PPS bundled rate for calcimimetics and drugs or biologicals not within existing functional categories, it could rely upon this provision for the authority to provide new money for drugs or biologicals that come within an existing functional category,

[16] *See id.,* § 1395rr(b)(14)(F).
[17] *Id.*
[18] *See id.,* § 1395rr note.

particularly for new therapies that are clearly not reflected in the bundle and base rate established for the 2011 implementation.

Some might argue that the general authority to create the ESRD PPS prevents new money to be added to the base rate for any item or service that would come within the ESRD PPS. That reading of the statute is too narrow. The Congress established the requirement for a single payment amount for the provision of renal dialysis services provided by providers of services or renal dialysis facilities.[19] It limited the payments in 2011 to 98 percent of the estimated total amount of payment for these services that would have been made if the new PPS system had not been implemented.[20] It does not limit any future year, nor does it indicate that if new items are defined to be renal dialysis services that CMS is prohibited from adding new money to the base rate. Under the well-established doctrine of *expressio unius*, the expression of the limitation of the rate in 2011 suggests the exclusion of restrictions on the base rate amounts and total expenditures in future years.

In sum, CMS has sufficient authority to expand the drug designation policy to add new money to the ESRD PPS base rate for new drugs and biologicals, even if they come within existing functional categories. As we noted in the section on the calcimimetic policy, having appropriate data to assess utilization and allow practice patterns to stabilize is important for assessing how the base rate should be adjusted. Therefore, we also ask that CMS return to the original policy that the TDAPA period would be two to three years. This would allow CMS to collect at least two full calendar years of data, but use the most recent publicly available 12 months of data to determine the utilization before folding the product into the ESRD bundle.

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, just as occurred for calcimimetics. We ask CMS to take steps to ensure that there is adequate funding for innovative products in the MA program as well.[21]

V. KCP generally supports the ESRD PPS Update for 2021, but recommends that CMS address the unresolved problems with the case-mix and facility-level adjusters, as well as modify the price proxy for certain drugs and amend the cost reports to capture the Network Fee.

CMS proposes an annual update of 2.2 percent for the ESRD PPS base rate for CY 2021, which KCP supports. We recognize that CMS does not have the authority to eliminate the productivity factor adjustment from this calculation, but reiterate our concern that the

[19] 42 U.S.C. § 1395rr(b)(14)(A).
[20] *Id.* at § 1395rr(b)(14)(B).
[21] *See,* 42 C.F.R. §422.109.

overall negative Medicare margins and the experience of dialysis facilities argues against the idea that productivity can be improved year over year.

Similarly, with new drugs being added to the ESRD PPS, it is more important than ever to use the most appropriate price proxies for determining the base rate and update each year. Thus, KCP urges CMS to adopt 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.

KCP appreciates and supports the flexibility CMS proposes for applying the low-volume payment adjustment (LVPA). However, we continue to echo the concerns raised by MedPAC that the LVPA and rural adjuster overlap and are not appropriately targeted to the facilities that need the adjustments. 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 fewer than 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. While we appreciate the limited resources CMS has to implement major changes between the Proposed and Final Rule, we ask that CMS adopt this change in the Final Rule. CMS could issue a final rule with comment period to solicit input from stakeholders and not delay final implementation of the proposal for CY 2021. Part of this work should include modifying the methodology used to determine the adjusters as well.

Similarly, we encourage CMS to address the ongoing concerns with the case-mix adjusters. KCP has provided both clinical and analytical support for reforming these adjusters in previous letters. We were pleased that CMS convened a Technical Expert Panel (TEP) to review these adjusters. The clear message from TEP participants was to: limit the number of adjusters; target adjusters to patients whose care is actually more expensive in the dialysis setting; and avoid using adjusters taking money out of the system. 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 also ask, as we have in previous years, that CMS suspend the graduated age categories and replace them with two categories: (1) “less than 18 years old” and (2) “greater than or equal to 18 years old.” We also ask CMS to suspend the patient weight adjusters, which cancel each other out and do not provide accurate payments, until it has the time to address the methodological problems. KCP once again reiterates our willingness to work with CMS to develop the appropriate adjusters so that they could be proposed for the CY 2022 payment system rulemaking.

Finally, KCP encouraged CMS to 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.

VI. 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. While we support the proposed base rate, we ask that CMS provide more information to the kidney care community about how it is monitoring the AKI benefit. As the Agency and community acknowledged when the AKI benefit was first created, 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.

We also ask that CMS provide clarification in the final rule regarding two policies related to the pandemic. 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 public health emergency.

Similarly, some hospitals are discharging COVID-19 patients to skilled nursing facilities. We appreciate the guidance that indicates that dialysis facilities are permitted to provide services within the SNFs, but we want to clarify that this guidance also allows reimbursement for services provided to AKI patients discharged from hospitals and sent to SNFs.

VII. KCP supports patient modality choices and suggest specific policy changes within CMS's current authority to support expanding the number of patients who select home dialysis modalities.

During the last several years, KCP has sought to work with the federal government to remove barriers that make it more difficult for patients who want to select home dialysis

to do so. Thus, KCP is pleased that the Administration has prioritized encouraging more Medicare beneficiaries who require dialysis to select home dialysis modalities. As the GAO has noted, there are many reasons that patients may not select these modalities, most of which center around socio-economic issues. However, we recognize that there are steps CMS can take to help expand education and incentives to meet the goal of aligning home dialysis resource use with payment. With this goal in mind, we encourage CMS to adopt the following policies:

- Expand the Medicare Kidney Disease Education program to: (1) allow dialysis facilities to provide kidney disease education services under certain circumstances; (2) permit physician assistants, nurse practitioners, and clinical nurse specialists, in addition to physicians, to serve as referral sources for the benefit; and (3) to provide access to these services to Medicare beneficiaries with Stage 5 Chronic Kidney Disease (CKD) not yet on dialysis.

- Remove Fraud and Abuse barriers by:

    - Allowing ESRD facilities to provide education of CKD patients; and

    - Providing safe harbors from Stark/anti-kickback laws for providers who furnish telehealth equipment needed for home dialysis.

- Support collaboration among providers by waiving fraud and abuse restrictions so that:

    - Health care providers are allowed to share population health tools and predictive modeling technology to support practitioners with management of CKD patients and transplant progression; and

    - Licensed health care professionals should be allowed to provide education on all modalities to a hospitalized patient with kidney failure at the request of the patient's care team, including discussion of in-center and home dialysis modalities, management of kidney failure without dialysis, and kidney transplantation. The decision regarding modality choice should be the result of a shared decision making process between the patient and the nephrologist.

- For the duration of the COVID-19 pandemic, waive the requirement that CMS reimburse providers for providing care to AKI patients only when they receive in-center hemodialysis.

- Support flexibilities related to telehealth that are being provided during the pandemic, but maintain the requirement for at least one physician visit each month to be an in-person visit. These flexibilities should provide support so that

socio-economic barriers can be eliminated for patients who seek telehealth visits.

- Create incentive payments for nephrologists and facilities linked to home dialysis adoption.

    - Increase the physician payment for home training from $500 (which has been the rate for more than 30 years) to $1750, which is the $500 amount updated for current dollars. The initial $500 could be paid at the outset, while the increase of $1250 could be paid out after a patient has completed six months of successful home dialysis treatments.

    - Establish bonus incentive payment for surgeons, hospitals, and surgery centers to bring reimbursement for peritoneal dialysis (PD) catheter placement in line with AV Fistula reimbursement.

- Collect social determinant of health data using Z-codes to account for and report on the most common non-clinical barriers to home dialysis, including housing or financial insecurity, minimal caregiver support, other mental and certain physical illnesses, or advanced age to provide information about these barriers and develop policies to overcome them and to be able to set target rates of home dialysis adoption.

- Eliminate barriers created by ESRD QIP and DFC/Five Star measures to allow for more transparency for patients seeking home dialysis performance information.

    - Eliminate the pooled adequacy of dialysis measure and replace it with the four individual dialysis quality measures to allow patients to see facility performance on home and pediatric dialysis, rather than have them rolled up in a single measure that disincentivizes the use of home dialysis. Addressing the problem of small numbers for pediatric facilities should not be resolved in a manner that eliminates transparency related to home dialysis care.

    - Expedite the process for establishing a home dialysis CAHPS, as well as a pediatric CAHPS.

In addition, we encourage CMS to work with KCP and support efforts to engage the Institute of Medicine (IOM) to study the barriers that exist to increasing the number of individuals with ESRD who elect to receive home dialysis services or other treatment modalities.

KCP encourages CMS to reaffirm that physicians have the ability to prescribe the dialysis dose that is medically necessary for their patients and to preserve the flexibilities

that Medicare Administrative Contractors (MACs) have to reimburse for more than three treatments per week with medical justification.

Since its inception, KCP has appreciated CMS's willingness to work with us to improve and refine the payment system. As an organization that represents patients, physicians, nurses, other health care professionals, manufacturers, and dialysis facilities from more than 30 different kidney care organizations throughout America, we have focused on helping the federal government maintain its strong and unique commitment to Americans living with kidney failure. As the Administration continues to seek ways to make home dialysis an option for more patients, we encourage CMS to work with KCP on the recommendations identified in this letter to align the payment system with the goal of helping patients select home dialysis, when it is the right option for them.

VIII. 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,

John Butler
Chairman

Appendix A: KCP Members

Akebia Therapeutics
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Pediatric Nephrology
Amgen
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
National Kidney Foundation
Nephrology Nursing Certification Commission
National Renal Administrators Association
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care
Vertex
Vifor Pharma