KIDNEY CARE PARTNERS

December 20, 2019

Francis J. Crosson, M.D.
Chairman
Medicare Payment Advisory Commission
425 I Street, N.W. Suite 701
Washington, DC 20001

James E. Mathews, Ph.D.
Executive Director
Medicare Payment Advisory Commission
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Dear Chairman Crosson and Executive Director Matthews:

I am writing on behalf of Kidney Care Partners to provide what we hope are constructive comments about the recent discussion by the Medicare Payment Advisory Commission (MedPAC or Commission) of the Medicare End Stage Renal Disease (ESRD) program. In addition, KCP would like to thank you, the staff, and the Commissioners for your thoughtful and in-depth review of the program each year. While we are pleased that the Administration has recently focused its attention on the issues facing patients living with kidney disease and kidney failure, we sincerely appreciate MedPAC's consistent engagement on these issues. KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with chronic kidney disease (CKD), including irreversible kidney failure, known as End-Stage Renal Disease (ESRD).

Protecting access to high quality care for individuals living with kidney disease and kidney failure remains KCP's highest priority. To that end, we would like to share additional background around two issues in particular that arose during the December 6 Commission meeting.

I. Recent Increases in Margins

During the discussion, Ms. Ray presented the Medicare margin for 2018 as 2.1 percent and the projected 2020 margin as 2.4 percent. As many of the Commissioners noted, these margins are a dramatic change from the trend of small or negative margins MedPAC found between 2014 and 2017. We were pleased that the Commissioners focused on the potential policy changes that might be driving the margin up, especially in the short term. On slide 10 of the presentation deck, the basis for the dramatic swing is identified as the transitional drug add-on payment adjustor (TDAPA).

We understand that MedPAC staff has also calculated the margin excluding TDAPA, which resulted in a much lower margin. During the January meeting, it would be helpful if that margin could also be presented to the public, because it appears that it may be one of the key factors considered by the Commission when making a recommendation about the

TDAPA policy. In addition, we ask that MedPAC share an estimated impact of the margin given the shift of the TDAPA rate from Average Sales Price (ASP)+6 percent to ASP+0 percent. This data point is important for understanding how the margin will be impacted by the change in the policy given that CMS finalized the ASP+0 percent rate for the TDAPA for certain new drugs and biologicals as well. We also ask MedPAC to recognize and take into account the introduction of generic calcimimetics that are now on the market and the reduction of the ASP in 2020.

In addition, it is important to recognize that the increase in Part B spending is due to the shift of the oral calcimimetics from Part D. We suggest that MedPAC review the Part D expenditures for calcimimetics prior to the shift to Part B and then compare the expenditures. Based upon work from The Moran Company, the actual Medicare expenditures for calcimimetics were reduced once they were folded into Part B.

As we had discussed in meetings earlier this year, KCP anticipated that, as then structured, TDAPA would increase the margins in the short-term. Our concern is that this increase will be short-lived. In terms of the oral-only TDAPA, as Ms. Ray pointed out, there is currently no money and no clinical alternative to calcimimetics in the ESRD PPS bundle. CMS policy states that new dollars will be added to the bundle when the drugs are added, which could be as early as 2021. Yet, CMS has not specified how it plans to determine the amount it will add to the bundle. Thus, we caution MedPAC, as well as other policy-makers (including the Administration and CMS) from placing too much value on the margin that includes the TDAPA for oral-only drugs. Rather than react to the short-term impact of the add-on, we encourage MedPAC, as it has done in the past, and other policy-makers as well, to take a measured and long-term approach that recognizes the temporary nature of TDAPA, as well as the change in the rate that will likely reduce the projected margin significantly.

As noted in the next section, KCP would like to work with the Commission to develop proposals for ways the Administration could refine TDAPA that promotes innovation in a sustainable and responsible manner. The historic margin analysis shows a stagnation in the base rate that has dis-incentivized the development of truly innovative products during the past decade. We offer a way to address this systemic problem in the next section.

II. TDAPA Policy

Adequate funding is needed to achieve the goals of incentivizing true innovation, increasing the number of patients selecting home dialysis, and promoting transplantation options. Achieving these goals is critical to continued improvement in the quality of care provided to, and quality of life of, patients. The Administration rightly recognizes the need to incentivize innovation and has initiated the Kidney Accelerator (KidneyX) for research and has adopted the TDAPA and the transitional add-on payment adjustment for new and

innovative equipment and supplies (TPNIES) for payment. However, as the analysis presented in December shows, the initial implementation of the oral-only TDAPA highlights the challenges of the policies and the need for refinement. We encourage the Commission to take the time to thoroughly examine the three different TDAPA policies and TPNIES policy before making a recommendation that might address the immediate concern, but does not provide a long-term solution that is necessary to protect patient access to innovation. Specifically, we encourage MedPAC to analyze the existing functional categories, the definitions of each one, and the dollars CMS identified as being attributed to each category before making a blanket recommendation that the TDAPA should be eliminated for drugs or biologicals that fall within existing functional categories.

First, KCP shares the Commissioners concerns about the potential inappropriate incentives TDAPA may create. That is why in our comment letters to CMS (even prior to the adoption of TDAPA) we urged CMS to exclude generics and biosimilars that fall within functional categories from TDAPA. These products, by definition, have competitor products already funded through the ESRD PPS rate and should be able to compete within the bundle, as they would in other health care markets. We also encouraged CMS to apply TDAPA to only truly innovative products and suggested the use of a "substantial clinical improvement" standard that we defined using specific categories of products that would address gaps in current treatment or demonstrate improved patient outcomes or improved safety. While it is not a perfect match to the KCP recommendations, the CMS decision to limit TDAPA by excluding generics and the following categories of drugs and biologicals is a step in the right direction. We encourage the Commissioners to review the exclusion list finalized by CMS in November, because we believe it will address several of the concerns raised during the December discussion about "me too" or similar types of products.

Specifically, the final rule excludes drugs with the following FDA NDA category:

- **Type 3** (new dosage form of an active ingredient that has been approved or marketed in the United States by the same or another applicant but in a different dosage form)
- **Type 5** (changes in inactive ingredients that require either bioequivalence studies or clinical studies for approval; duplicates existing drug; active ingredient or active moiety that has been previously approved or marketed in US; combination product that differs from a previously marketed combination by the removal of one or more active ingredients or by substitution; product differs in bioavailability; or new plastic container)
- **Type 7** (drug product that contains an active moiety that has not been previously approved in an application, but has been marketed in the US)
- **Type 8** (Over-the-counter switch)
- **Type 3** (see above: new dosage form) **with Type 2** (new active ingredient) **or Type 4** (new combination)

- **Type 5** (see above: change in inactive ingredient) in combination with **Type 2** (new active ingredient)
- **Type 9 when the "parent NDA" is a Type 3, 5, 7 or 8** (see definitions above)

The types of drugs that remain eligible are:

- **Type 1** (new molecular entity);
- **Type 2** (new active ingredient);
- **Type 4** (new combination), if at least one of the components is a Type 1 or a Type 2;
- **Type 9** (new indication or claim, drug not to be marketed under Type 9 NDA after approval); and
- **Type 10** (new indication or claim, drug to be marketed under Type 10 NDA after approval).

Second, KCP has long supported the bundle and actually encouraged CMS to work closely with the kidney care community to develop larger bundles that would allow for improved care coordination and reductions in overall Medicare spending for the ESRD population. However, the current 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, which the historic negative Medicare margins show. While an appropriately targeted TDAPA would allow the community to adopt a new product, it does nothing to address the underfunding of the program or to provide a sustainable pathway for the permanent adoption of new products. It is critically important that CMS get the post-TDAPA policy correct so that providers are paid appropriately, which would result in more stable margins.

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 the Commission, 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. During the TDAPA period, only truly innovative products (regardless of their relationship to an existing functional category) would receive the add-on. 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.

The limitations on TDAPA 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. 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 might be appropriate to add some amount less than the full cost to account for dollars if the drug is a true competitor for another product already in a functional category in the bundle and there are sufficient dollars associated with the functional category.

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. As Table A also shows, there is little to no money designated for the vast majority of these categories, which creates a substantial barrier for any new product that would have to try to compete. KCP encourages CMS and MedPAC to monitor the effectiveness of policies aimed at delivering new products to beneficiaries through the ESRD PPS, including those related to existing or newly introduced non-TDAPA products. If truly innovative products are not reaching beneficiaries due to lack of adequate funding through the PPS, CMS should make an adjustment to the ESRD PPS to ensure products with high clinical value can reach patients to advance the standard of care.

KCP has recognized that additional payment methodologies may be necessary for those innovative drugs that are not used by the average patient and are high cost. One approach is that CMS could bundle the product, but instead of spreading the dollars added to the base rate across all facilities, CMS could establish a pool from which facilities using the new product could be paid if they administered the product to a specific patient. This type of policy would not be a separate add-on outside of the bundled rate. It is important that CMS have options available for addressing the unique situation of such innovative products to protect access for patients.

By limiting TDAPA to only truly innovative products, CMS would expend fewer dollars overall. The money saved could be used to support adjusting the bundled rate for truly innovative products when their pass-through period ends. Yet, such an appropriate should also recognize that many of the existing functional categories were designed to encompass drugs that have been provided for decades, some of which may not even be effective for the majority of patients. Because of this stagnation, the base rate cannot adequately support truly innovative products even if they technically meet the definition of an existing functional category.

KCP believes that an approach such as the one we suggest is necessary to achieve the goal of incentivizing and 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 against which to balance the changes in that one rate. 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.

Since its inception, KCP has sought 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 educational initiatives, such as the Kidney Disease Education benefit. Consistent with these efforts, we ask MedPAC to work with the kidney care community and to avoid a hasty recommendation based on a reaction to the oral-only TDAPA. Instead, we encourage MedPAC to evaluate the ESRD PPS in its totality and consider ways that the system could incentivize innovation while being true to the principals of bundling. We believe that our recommendations strike that balance, but would welcome the opportunity for further discussions with the Commission.

III. Other Comments

In addition to these two issues that related to the potential recommendations for consideration in January, KCP would like to offer a few additional suggestions.

First, we appreciate MedPAC's consistent support for allowing all dialysis patients to have the opportunity to enroll in Medicare Advantage (MA) plans. As anticipated, more patients currently are enrolling in MA plans, and we anticipate that in 2021 the enrollment will further increase, as eligibility for MA plans is expanded for prevalent ESRD beneficiaries. Given the growing MA population, we suggest that MedPAC consider capacity by looking at the MA as well as the fee for service treatments.

Second, we encourage MedPAC to include the Low-Volume and Isolated (LVI) facility adjuster presented during the October meeting in the recommendation for the March 2020 *Report to the Congress.*

Third, as MedPAC considers the cost of care for dialysis patients and seeks ways to reduce expenditures, we encourage the Commission to examine what the kidney care community and health policy experts agree is the optimal means to address growing costs, specifically by providing care to CKD patients <u>before</u> they progress to kidney failure. In addition, improving care coordination is another critical factor to improve patient outcomes and reduce overall Medicare expenditures. Currently, the Stark and anti-kickback laws create barriers that impose restrictions on how physicians and dialysis facilities can interact, which restrict their ability to coordinate care. We are pleased that the OIG and CMS have released proposed rules to protect care coordination activities. We encourage MedPAC to support the application of these protections to dialysis facilities and nephrologists. As the ESCO results showed, care coordination for dialysis patients can reduce costs and improve care.

Finally, we again encourage the Commissioners to consider the impact of bad debt on the overall stability of the Medicare ESRD program. There is a high rate of unrecoverable bad debt associated with drugs and biologicals. Many patients are unable to pay the cost-sharing obligations for many reasons; for example, not all States require insurers to provide access to Medigap insurance and other States do not pay the beneficiary's 20 percent when the beneficiary is a dual eligible. The unrecovered bad debt has a substantial and negative impact on the system and should be part of the analysis evaluating the adequacy of payments.

IV. Conclusion

Once again, KCP appreciates the continued engagement and thoughtful work MedPAC undertakes each year to evaluate the Medicare ESRD program. There are many areas where the data have directed the Commission and KCP to make similar recommendations, and we look forward to continuing to pursue the policy reforms in these areas as well. We reiterate our suggestion that MedPAC provide the additional margin analyses highlighted above and take a cautious approach as to how to use the margin analysis that includes the oral-only TDAPA for determining policy recommendations. We also encourage the Commission to take additional time to assess all aspects of TDAPA and TPNIES before making a recommendation that may seem appropriate for a current concern, but be short-sighted for the long-term solution needed to promote innovation. As always, we appreciate your willingness to engage with the community. Please do not hesitate to contact Kathy Lester, our counsel in Washington, if you have any questions or would like more detail about our comments or recommendations.

Sincerely,

John Butler
Chairman

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
Baxter
Board of Nephrology Examiners and Technology
Cara Therapeutics
Centers for Dialysis Care
Corvidia Therapeutics
DaVita
DialyzeDirect
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic
National Kidney Foundation
Nephrology Nursing Certification Commission
Otsuka
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare
U.S. Renal Care