KIDNEY CARE PARTNERS

August 23, 2018

The Honorable Alex M. Azar, II
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Secretary Azar and Administrator Verma:

Kidney Care Partners (KCP) appreciates the opportunity to provide comments on the Proposed Rule entitled "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) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS" (Proposed Rule).[1]

KCP is an alliance of members of the kidney care community that includes patient advocates, kidney care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both CKD and irreversible kidney failure, known as ESRD.[2]

In this letter, KCP provide comments on the proposed CY 2019 ESRD update, responds to the solicitation for information on transplant and modality requirements, and the Acute Kidney Injury (AKI) KCP payment proposal. We also reiterate our concerns related to the implementation to date of the Transitional Drug Add-on Payment Adjustment (TDAPA) and urge CMS to provide more clarity in this area. In our previous letter dated August 10, 2018, KCP provided comments on the drug designation process and the payment adjuster proposals of the CY 2019 ESRD PPS, which we briefly summarize in Section I of this letter. We are providing our comments on the ESRD Quality Incentive Program (QIP) proposals in separate letters as well.

[1] 83 *Fed. Reg.* 34304 (July 19, 2018).
[2] A list of KCP members is provided in Appendix A.

I. Brief recap of the KCP August 10, 2018, comment letter supporting applying TDAPA to new renal dialysis drugs and biologicals that are not defined as generics or biosimilars by the Food and Drug Administration (FDA) and seeking modifications to the drug designation process.

A. Recap of KCP recommendations from August 10, 2018, comment letter on the proposed drug designation policy.

Supporting true innovation for patients living with kidney failure and who rely on thrice-weekly dialysis treatments to survive is a top priority of this Administration (as evidenced through KidneyX) and the kidney care community. In our August 10, 2018, letter, KCP provided detailed comments about how the ESRD PPS payment needs to be modified to support this commitment to innovation. In that letter, we support applying TDAPA to new renal dialysis drugs and biologicals that are not defined as generics or biosimilars (using the FDA definition of those terms). We also recommended that CMS learn from the problems experienced in the hospital outpatient setting and rely upon the Average Sales Price (ASP)+6 percent for the TDAPA rate and that CMS obtain two full calendar years of claims data before determining whether to fold a new renal dialysis drug into the ESRD PPS.

As noted below, KCP members continue to experience difficulties with the implementation of TDAPA, particularly related to the transition of oral drugs from payment under Medicare Part D to Medicare Part B and ask that CMS assist in resolving these problems given that calcimimetics remain under TDAPA for at least one more year. However, as noted in the August 10, 2018, letter, KCP recommends that CMS also ensure that it has adequate information to fold calcimimetics into the ESRD PPS by also obtaining two full calendar years of claims data, which would lead to a slightly longer than two-year TDAPA period for calcimimetics as well.

In the August 10, 2018 letter, KCP recommends a modified approach to how CMS evaluates new renal dialysis drugs and biologicals for purposes of including them in the ESRD PPS bundle. These recommendations seek to create incentives for truly innovative products and not reward only minimal changes in products. We believe that without changes to the drug designation process, there will be extremely limited interest by investors and manufacturers in developing truly innovative products for patients who must rely on dialysis treatments.

In sum, KCP recommends the following methodology for evaluating renal dialysis drugs and biologicals:

- First, consistent with KCP's recommendations around TDAPA, generics and biosimilars (as defined using the FDA's definition) should be folded into the existing functional categories without new money.

- Second, CMS should assess, based upon the utilization and prescribing data collected during the TDAPA period, whether the drug is provided to the average patient, which CMS uses to define the scope of the bundle.[3] If only a small portion of patients use the product, then it should not be added to the bundle. Incorporating such products into the bundle would create the wrong incentives. Providers who use the product will always be reimbursed less than it costs to provide and providers who do not use the product will receive a windfall (albeit a small one). Bundling a product that is medically necessary for only a small percentage of patients only disincentivizes its use.

- If the utilization is such that the renal dialysis drug or biological should be bundled, KCP supports adding new money to the bundle when a new renal dialysis drug or biological that is not in an existing functional category is incorporated.

- However, KCP outlines in the August 10, 2018, letter, that it is not appropriate to assume that the bundled base rate is sufficient to support adding new renal dialysis drugs and biologicals if CMS determines they are in existing functional categories. New money should be added to the bundle for new drugs and biologicals that CMS determines are in existing functional categories,[4] when the new products can be differentiated – shown to be truly innovative – from existing therapies. KCP recommends that CMS look at the following factors to determine when a new renal dialysis drug or biological is differentiated from existing products to warrant new money be added to the ESRD PPS base rate. Specifically, the renal dialysis drug or biological achieves one of the following priorities:

    - Fills a treatment gap (addresses an unmet medical need) for renal dialysis patients.
        - CMS could solicit input from the kidney care community to identify these gaps and use that as a guardrail to ensure the appropriate application of this factor.

[3] 83 *Fed. Reg.* at 34314.
[4] As described below, part of this analysis should include an evaluation of whether the utilization during the TDAPA period supports adding the product to the bundle.

- A subcategory of this factor are drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug's label. There is clearly a treatment gap when the FDA has not approved a product for a specific CKD/ESRD/dialysis-related condition.

- Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material (including within the clinical pharmacology and study portion of the FDA label, sections 11 and 14 or any other section of product labeling) and that do not fit within a single existing functional category. These drugs and biologicals may offer multiple advantages over existing products.

- Drugs and biologicals that demonstrate a significant improvement in safety over products currently available in the bundle.

- Drugs and biologicals, that based on FDA labeling that, have demonstrated clinical superiority to existing products in the bundle.

- Drugs and biologicals that improve priority outcomes, such as:
  - Decreasing hospitalizations;
  - Reducing mortality;
  - Improving quality of life (based on a valid and reliable tool);
  - Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);
  - Addressing patient-centered objectives (including patient reported outcomes once they are developed and used by the FDA in its review of drugs and biologicals); or
  - Reducing side effects or complications.[5]

In making these recommendations, KCP seeks to help CMS establish clear guardrails that support truly innovative products while protecting the integrity of the bundle.

As noted our August 10, 2018 comment letter, KCP has raised concerns about the functional categories. While we appreciate that they have been part of the ESRD PPS since its inception, the current categories, if applied in a manner that does not acknowledge the development of new products, will stifle innovation to treat the core conditions that

[5]Current legislation being considered by the Congress includes criteria such as these. *See* H.R. 5997 "Ensuring Patient Access to Critical Breakthrough Products Act of 2018" introduced by Reps. DelBene (D-WA), Walorksi (R-IN), Sewell (D-AL), Bilirakis (R-FL), and Cardenas (D-CA).

dialysis patients experience. Any policy that locks the bundled payment amount at current levels removes any incentive for developers, manufacturers, and investors to innovate in this area. The bundle should be defined, in-line with its original intent, around products that are "associated with the dialytic treatment" to align with this intent. Eliminating the broader scope of the functional categories by further narrowing them and centering the bundle on services and items associated with the dialytic treatment align the ESRD PPS more closely into line with the policies in other Medicare prospective payment systems that do not use functional categories for drugs and biologicals and define the bundle in a manner consistent with the services provided in the dialysis facility under the PPS.

B. Ensuring TDAPA implementation going forward

KCP continues to support the use of TDAPA to allow for sufficient time for the kidney care community to evaluate new renal dialysis drugs and biologicals as they come to market. However, the use of TDAPA in the unique context of the transition of an oral-only drug into the ESRD PPS has presented serious challenges, many of which remain unresolved. We ask that CMS take the necessary steps and issue clarifying guidance before the end of the year to ensure that the problems experienced during the first year of TDAPA will not be repeated in the second year.

First, the dialysis facility claims policy for oral calcimimetics continues to require facilities to attest on the claim to the amount of oral medications consumed. While some beneficiaries may take these drugs in their facility, the vast majority take them at home. This fact makes it impossible for facilities to attest to the amount of drug taken. While the per treatment "unit" of payment aligns with the dialysis treatment, there is a mismatch when it comes to oral medications. These drugs are consumed daily by the patient and not specifically and only on the day of treatment. For home patients this has resulted in denial of payment for medications consumed because the MACs general limit payment to only allowed treatments for payment which are almost always less than delivered treatments. CMS should conform payment for oral medications across the entire Medicare population and should not treat dialysis patients differently, this results in a natural payment shortfall for dialysis providers. KCP asks that CMS change this policy and require facilities to claim the amount of the drug dispensed. This change would align the ESRD PPS policy with the one CMS already applies to skilled nursing facilities.

We also ask CMS to state that facilities should be allowed to claim products that are dispensed to beneficiaries rather than the amount that they expect the patient to take within the billing month. CMS should reimburse facilities for the complete prescription dispensed in the same billing month. Because CMS divides the reimbursement for a month of calcimimetics by the number of each treatment on the claim and requires the amount consumed to be listed, questions arise about how facilities can claim drugs that they dispensed in good faith, but that may go unused because a beneficiary dies, is hospitalized,

or receives a transplant. Oral drugs also go unused when a beneficiary's prescription changes. In addition, when a beneficiary changes his/her facility, there is currently no way to claim the remainder of the cost of providing the drug, even if the beneficiary uses it because there are no more treatment claims submitted by the facility that provided the drug. In the end, KCP asks that CMS treat the dispensing of oral medications in the same manner that it treats them in other parts of the Medicare program and allows facilities to claim and be reimbursed for the amount of drug dispensed. If a provider provides services to a beneficiary, Medicare should reimburse the provider for doing so.

Finally, we ask that CMS ensure that the calcimimetic policy is aligned across the PPS and the Medicare Advantage (MA) plans. While guidance has been provided informally to dialysis facilities, the lack of a clear document from CMS to MA plans has created some confusion and resulted in considerable reimbursement problems by some plans. It is unclear why the informal guidance has not been made public; KCP strongly encourages CMS to publish it immediately. When a product is added to the bundle or TDAPA is applied, then MA plans should be required to cover it and not allow a three-year gap to occur. CMS recognized this need in the last MA rate notice. We ask that CMS formalize a process to ensure that MA funding by CMS is timely and consistent with material changes in the ESRD PPS.

C. KCP seeks clarification as to the treatment of new devices related to the treatment of ESRD.

As noted in our August 10, 2018 letter, KCP supports developing a policy to provide clarity as to the payment policies related to new renal dialysis drugs. We ask that CMS also provide clarity on how it will incentivize the development of new device that it may determine come within the ESRD PPS. To the extent there is such a device, KCP asks that at a minimum, CMS apply a pass-through payment to new devices when they are determined to be within the bundle and then evaluate them based on the data obtained during that period to determine whether it is appropriate to add them into the bundle and if so whether new money should be added as well. We welcome the opportunity to engage with CMS to develop a more detailed policy. In the short-term, we ask that CMS indicate in the final rule that it will provide such a pathway and work with stakeholders in future-rulemakings to further define it.

II. KCP supports the CY 2019 ESRD update to the market basket and rebasing the PPS to base year CY 2016, but briefly reiterates our request for CMS to work with the kidney care community to address the long-standing problems with the ESRD PPS adjusters.

A. KCP supports the proposed update to the CY 2019 ESRD PPS market basket and rebasing to CY 2016, but asks CMS to identify a better proxy for non-ESAs that are not over the counter (OTC) vitamins.

KCP supports the proposal to rebase the ESRD PPS market basket to the base year CY 2016. As we have noted in the past, our concerns lie with any reductions to the ESRD PPS that looks at single inputs rather than the bundle as a whole. It is important to make sure that increases in labor-related and other cost increases are taken into account if utilization in other areas seems to decrease.

Generally speaking, KCP also supports the proposed market basket update. We understand when CMS applies the productivity adjuster, it is implementing the requirement at 42 U.S.C. § 1935rr(b)(14)(F)(ii). We also recognize that the statute requirements the productivity factor to be determine consistent with the formula set forth for all Medicare payment systems at 42 U.S.C. § 1395ww(b)(3)(B)(xi)(II).

> The productivity adjustment described in this subclause, with respect to a percentage, factor, or update for a fiscal year, year, cost reporting period, or other annual period, is a productivity adjustment equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

However, 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* estimated that the margin is 0.5 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."[6] 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."[7] 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.

KCP supports the proposal to increase the labor-related share for CY 2019 to 52.3 percent. As our members have discussed, the cost of labor is increasing. It is critically important that the ESRD PPS recognizes these increasing costs and adjusts the payment amount.

Finally, 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

[6] 2018 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS at 3 (available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf)
[7] *Id.*

(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.

B. KCP briefly reiterates the August 10, 2018, recommendation that CMS should address the ongoing problems with the case-mix adjusters to promote adequate payment rates; while we appreciate the effort to reduce the burden of the comorbid adjusters, the proposal does not achieve that goal.

As KCP describes in detail in the August 10, 2018, letter, it is important that CMS and its contractor engage actively with the kidney care community and, consistent with MedPAC's recommendations, resolve the analytical problems that have led to payment adjusters that do not meet the objective of identifying higher cost patients. Therefore, we appreciate CMS's statements that it has asked its contractor to convene a group to evaluate the methodology and adjusters. We ask that CMS provide sufficient scope to the contractor to ensure a meaningful review of the analysis that replaces the two-equation regression model and is open to eliminating existing adjusters, as the data may indicate. We also encourage CMS to allow the contractor to discuss various sources of data to ensure that the best data sources are ultimately used and to protect as much as possible against variables that correlate with one another.

In the meantime, we ask that CMS:

- Eliminate the use of all co-morbidity case-mix adjusters for CY 2019, consistent with the previous KCP and MedPAC recommendations; while we appreciate the effort to try to reduce the burden on documenting these conditions for claims reporting, the reality is that dialysis facilities do not diagnose these conditions and, therefore, regardless of the specific documentation required are not able to have adequate information to support a claim unless it is provided by another provider, which simply does not occur and remains unlikely to happen.

- Suspend the use of the age and weight adjusters for CY 2019 and until it can build a single equation model, as MedPAC has recommended.

- Eliminate the overlap between the rural and low-volume adjuster by relying upon a two-tiered low-volume adjuster policy, with the current low-volume adjuster being the first tier and the second tier applying to facilities with 4,001-6,000 treatments per year.

We also ask that any change to the adjusters be accompanied by a recalculation of the standardization factor so that the dollars represented by the adjuster can be returned to the base rate.

III. KCP does not support extending the outlier policy to composite rate drugs or biologicals eligible for TDAPA and encourages CMS to reform the outlier policy to prevent dollars from inappropriately coming out of the system.

KCP remains troubled that the outlier policy continues to under-estimate the outlier payment actually paid out. Each year since 2011, money has been inappropriately removed from the ESRD PPS overall funding that is not returned to the system. For example, the change from 2017 to 2018 is only from 0.78 to 0.80. Over time, the amount has resulted in a loss of $67 million since 2015 and $231 million since 2011, despite previous preamble discussions suggesting the outlier pool was improving. While this amount may seem trivial, given the negative margins of most dialysis facilities, every dollar that can go to patient care matters greatly.

In previous letters, we have recommended that CMS address this issue in part by relying upon the outlier payments for the higher costs it assumes are addressed through the comorbid case-mix adjusters. While we appreciate that CMS has proposed changing the documentation requirements, as noted above, this proposal does not address the underlying problem that other providers simply will not provide the information to support claims to dialysis facilities. In addition, we remain concerned that these adjusters do not actually reflect higher cost patients and money is being taken out of the system that is never returned to support patient care. However, to the extent patients with these conditions require more drugs or biologicals that are currently eligible for the outlier pool, outlier payments would be sufficient to address these higher costs.

In addition, as described in detail in our August 10, 2018, letter, KCP does not believe making the composite rate drugs that receive TDAPA payment eligible for the outlier pool will address the need for new money. Simply put, outlier payments are not designed to pay for drugs. They are meant for patients with unusually high costs.

Rather than continue this tortured exercise, we recommend that CMS: (1) eliminate the comorbid case-mix adjusters for CY 2019 and recognize that any patient with one of the

remaining conditions would use more of the drugs currently eligible for the outlier payment; and (2) if the outlier pool continues to be paid out at less than 1 percent, then CMS should reduce it to an amount closer to what is actually being paid out, even if that is less than one percent. KCP does not support extending the outlier payment to new drugs or biologicals that CMS would classify being within the existing functional categories. It would be inappropriate to do so because outlier payments are simply not designed to pay for drugs and biologicals that are regularly used. Instead applying the guardrails outlined in our August 10, 2018, letter and briefly reiterated in Section I, CMS should add new money to the base rate for these products when appropriate.

IV. KCP strongly supports efforts to increase patient modality choice, including home dialysis and increasing the number of transplants; however, current ESRD PPS payment policies (including the Conditions for Coverage (CfCs)) are not the barrier to achieving these goals.

KCP continues to support efforts increase dialysis modality options for patients and ensure equal access to them, as well increase opportunities for transplant. Achieving these goals is one of the reasons KCP advocated for aligning the home and in-center dialysis payments and was pleased when CMS adopted our recommendation to do so. KCP has also supported the current requirements in the CfCs and our members take them very seriously.

As MedPAC has noted, there has been a steady rise in the use of home dialysis since these changes were implemented. However, as MedPAC also recognized shortages in the solution used for PD has flattened that growth. Home hemodialysis has growth has been slower than anticipated because of the uncertainties associated with the payment policies around more frequent dialysis. Noridian's decision to pay for only three sessions and the recent Local Coverage Determinations (LCDs) issued by the Medicare Administrative Contractors (MACs) to restrict more frequent dialysis, will likely exert downward pressure on the future expansion of this modality. As KCP has commented to the MACs, medically justified more frequent dialysis leads to improved clinical outcomes and supports the use of HHD. CMS could help address both of these issues by: (1) developing a process with the FDA to address fluid shortages more quickly in the future; and (2) promoting a policy that support more frequent dialysis.

Another policy CMS could refine to improve modality selection is the Kidney Disease Education (KDE) benefit. As the 2015 GAO report noted, the KDE benefit is not effective today, in large part because of its inadequate payment rate. CMS should ensure adequate payment for the benefit and emphasize modality education as part of it. Also, while dialysis facilities are well equipped with the interdisciplinary beneficiary teams to provide the benefit, current law excludes them. CMS should address this problem by piloting a KDE benefit program that allowed dialysis facilities to provide and be reimbursed for KDE services and evaluate its impact on the number of beneficiaries who select home dialysis.

We also recommend that CMS eliminate the pooled Kt/V measure in the ESRD Quality Incentive Program (QIP) and return to the individual in-center and home dialysis measures of dialysis adequacy. The pooled measure hides facilities' performance on home dialysis from patients and consumers. Having the individual Kt/V measures, as originally used in the ESRD QIP, would incentivize the use of home dialysis by creating appropriate transparency in terms of the quality of care being provided. The lack of a home dialysis tool for measuring patient satisfaction also reduces transparency. Consistent with our ongoing work on the ICH CAHPS measure, KCP recommends moving more quickly to adapt the current measurement tool to support home dialysis patient surveys. Having a home dialysis CAHPS tool would also be an important step to addressing the weighting problems with the current QIP that penalize facilities providing home dialysis only.

Similarly, in the area of transplant it is important to include a transplant measure in the QIP that is actionable by dialysis facilities, as well as that would meet the other scientifically based criteria used to evaluate measures. While CMS has proposed two transplant measures in the QIP, the National Quality Forum (NQF) has rejected both measures as not meeting these criteria. Thus, if adopted, they will not incentivize transplant because they are so poorly designed that they do not measure what they were intended to assess. As noted in our April 10, 2018, comment letter on the ESRD QIP, KCP recommends that CMS prioritize developing an appropriate transplant measure that is actionable by dialysis facilities. A measure that recognizes what is actionable by facilities would better support the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The problem is not with facility assessment and evaluation, but with the criteria hospitals set for the waitlists. We recognize the need to avoid a "check-box measure," but believe that a transplant measure must be actionable for it to have a true impact on patient access to transplant.

We additionally recommend that CMS work closely with transplant programs to find a way to align and streamline the waitlist criteria. There is no centralized set of criteria and patients have to register with multiple transplant centers to improve their chances of finding a match. CMS may want to develop a pilot program to help patients navigate the complexities of the waitlist process as well. CMS should also carefully examine how transplant centers are evaluated in terms of outcomes and eliminate any metrics that encourage cherry-picking among patients.

CMS should consider the experience of the C.W. Bill Young Cell Transplantation Program, which is the national bone marrow and cord blood registry for the United States. Lessons learned from this highly successful program could be applied to improve matching with living donors, especially.

We also recommend that CMS work with the Congress to address the very real problem that many Medicare beneficiaries experience. Transplant centers will not include them on the waitlist unless they can prove they can pay for their immunosuppressive drugs post-transplant. Current law limits the length Medicare will cover these drugs for kidney transplants, which is a barrier to transplant.

In the end, we believe that the current CfCs are appropriate and being implemented by the vast majority of dialysis facilities in a manner that helps patients navigate the complexities of modality selection and transplant. However, there are very real barriers that patients face in both of these areas that are outside of the control of the dialysis facility and need to be addressed to see improvement beyond the margins.

V. KCP supports the separate payment rates for providing services to beneficiaries with Acute Kidney Injury (AKI) in dialysis facilities and reiterates our recommendation to evaluate the different costs associated with this patient population; KCP also seeks additional clarification about the AKI monitoring program.

KCP appreciates that CMS has announced the AKI payment rate as part of the Proposed Rule and provided the kidney care community with the opportunity to provide comments on the recommendations.

We are pleased that CMS indicated the Final Rule for CY 2017 that it agreed with comments from the kidney care community that it would "be developing formal monitoring programs for utilization to inform future payment policy."[8] We again ask that CMS provide more details about how these monitoring programs using claims information work and what CMS is seeing as part of this effort. As we have noted in previous letters, while the services provided to individuals with AKI may be the same, the frequency with which they are provided and the labor required to provide them may differ from that required for individuals with ESRD. As we learn more about the provision of services to these patients, it may become apparent that an "AKI adjustment" to the payment rate is necessary to address the differences in the services provided to AKI patients.

We also reiterate our ask that CMS explain its monitoring programs and how it will provide data from these programs to promote transparency in the program. Using current data and adjusting it upon the experience that will be gained in the coming years will be important to understanding the actual utilization of dialysis for AKI patients.

[8] 81 *Fed. Reg.* 77834, 77871 (Nov. 4, 2016).

VI. Conclusion

We are grateful for the commitment to innovation in the kidney space made by HHS through KidneyX, and we look forward to working with HHS on policies that can optimize the likelihood of changing the kidney failure treatment paradigm for the better. As noted, this letter augments the letter submitted on August 10, 2018, to the Proposed Rule. If you have questions or comments, please contact Kathy Lester at klester@lesterhealthlaw.com or (202) 534-1773. Thank you again for considering our recommendations.

Sincerely,

Allen Nissenson
Chairman
Kidney Care Partners

cc: Demetrios Kouzoukas, Principal Deputy Administrator for Medicare and Director
Laurence Wilson, Director Chronic Care Policy Group
Jeanette Kranacs, Deputy Director Chronic Care Policy Group
Jana Lindquist, Director Division of Chronic Care Management
Abby Ryan, Deputy Director Division of Chronic Care Management

Appendix A: KCP Members

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