



December 20, 2019

David Moore
Senior Director, Research
Acumen LLC
440 First Street NW, Suite 900
Washington, D.C. 20001

Re: End Stage Renal Disease Prospective Payment System Technical Expert Panel

Dear Mr. Moore:

I am writing to thank Acumen and CMS for convening the ESRD Technical Expert Panel (ESRD TEP) to assess several policies that apply to the ESRD Prospective Payment System (ESRD PPS). KCP is an alliance of members of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and ESRD.

We are pleased that CMS has decided to take a deeper look into the ESRD PPS and that Acumen is providing support through the ESRD TEP to obtain feedback from a small group of experts. Given the complexity of the issue and the importance of it to dialysis patients and the community as a whole who want to have a stable, predictable, and adequately funded payment system, we would like to recommend that future discussions and materials be open to more stakeholders.

In light of the recent meeting, we thought that the Acumen team might find it helpful to have some additional comments from KCP, particularly in relationship to the issues of adjusters (both patient level and facility level) and incorporating innovative drugs, biologicals, and devices into the payment system. We support the ongoing discussions around having a more accurate wage index for dialysis facilities, improving the outlier policy, and addressing the barriers (particularly those that may not be related to payment) to patient access to home dialysis. However, we have not presented a detailed analysis of the specific methodologies considered, particularly in the case of the patient level adjusters, at this time. We will follow up after the new year with additional thoughts and suggestions. More specifically, Mark Desmarias is reviewing the analytical suggestions in details and we plan to forward these comments to you in early January. However, knowing that work on the ESRD PPS proposed rule is underway, KCP would like to highlight a few key points to assist the ESRD TEP and CMS as you work through the policies potentially for the Calendar Year 2021 proposed ESRD rule.

I. Patient Level Case Mix Adjusters

KCP is pleased that the ESRD TEP is examining the patient level case mix adjusters. As our previous comment letters have highlighted, our members are concerned that, while well-intended, the current adjusters do not serve the basic rationale that supports the use of such adjusters in a payment system. The Moran Company's analysis of the existing system highlights the analytical problems with the current system. We will provide additional comments in January about the specific options presented to the ESRD TEP. However, we believe that regardless of the analytical path ultimately selected, patient level adjusters should serve the purpose of paying more for patients for whom it is more costly to care so as to avoid cherry-picking or lemon-dropping, as CMS highlighted in previous rulemaking. Given the clinical nature of this patient population, it is unlikely that any analytical model will find meaningful variation that warrant even a moderate number of case-mix adjusters.

Thus, we write today to encourage CMS and Acumen to focus on the payment system more comprehensively and practically. The Medicare ESRD program is unique in that it has a single bundled category, unlike the inpatient hospital setting that has more than 750 different MS-DRG bundles and other Medicare PPS systems that also have a substantial number of individualized bundle categories. The use of a single bundle suggests that there is little variability among dialysis patients. The data that Acumen shared with the TEP showed that with the exception of pediatric patients and the onset of dialysis, there is very little variation in cost and within the patient population, especially in terms of the existing patient level case mix adjusters. As KCP has noted in previous comment letters, particularly in relation to the co-morbid case-mix adjusters, the outlier pool is appropriately positioned to address differences in patient costs (particularly pharmaceutical use), but the current methodology has consistently overestimated the size of the outlier pool. (Please see section II for the discussion of the higher costs associated with facilities that have a low volume of treatments). Given the consistency of these results with those of MedPAC and stakeholders, KCP suggests that CMS and the ESRD TEP recognize the need to reduce the number of adjusters and focus work in this area on those categories that show meaningful variation. KCP would also recommend looking at BSA given the practical experience that patients who weigh more require a longer time on dialysis to remove fluid adequately.

We appreciate the desire to be as precise as possible; it is also important to consider the added cost to stakeholders and the federal government of doing so. It may be appropriate to add some data to the cost reports, for example, if the information will allow for meaningful changes in the payment rate; however, more granularity around many areas may simply add burden without benefit. As the hospital cost report experiences show, for example, unless a cost center is directly linked to the payment, the burden of providing the more granular information usually results in the data collected not being accurate and useable.

Today, the data do not exist in the cost reports or claims to support the current adjusters. Given the lack of variability in patients related to these adjusters, we do not think it would be appropriate to increase the data collection burden to support adjusters that do not represent higher cost patients. Cost categories, such as medical supplies, rent, and other operating costs, make up roughly 35 percent of facility costs and do not vary by patient. The cost of labor, as we have noted in previous letters, makes up about 45 percent of costs and varies primarily based on the number of treatments provided and how the scheduling treatments of individual patients relates to a facility's overall schedule. In our view, the variation of treatment times can be accounted for in terms of existing proxies (such as BSA) whose impact is well known and for which the data can be collected with little cost. A few other circumstances might warrant evaluation of a time in motion study to address costs associated with patients who require isolation, for example. While pharmaceuticals comprise roughly 15-20 percent of costs, the current adjusters do not reflect differences in costs that would not already be addressed appropriately by the outlier policy. Therefore, we ask CMS and the ESRD TEP to take a cautious approach and avoid recommendations that would be inconsistent with the Administrator's "Patients Over Paperwork" Initiative or that would increase the cost of administrative requirements without adding meaningful benefit to patients or providers.

KCP continues to believe that the structure of the payment system should promote dollars being devoted to caring for patients. The continued application of the current case-mix adjusters (including the facility-level adjusters discussed in the next section) results in the actual dollars CMS pays out for ESRD care to be significantly less than what the Congress had indicated it should be. While sequestration continues to be a driving source of underpayments, the underpayment amount attributable to other factors, which are due to a mismatch among adjusters frequencies assumed by the standardization factor compared to actual payment increased substantially in 2018 and remains high. The Moran Company estimates that taken together, the total underpayment for the PPS per treatment in 2018 was \$11.11. The underpayment due to the outlier pool was \$1.54 per treatment. Sequestration accounted for \$4.45 per treatment, with the ESRD Quality Incentive Program taking out 25 cents per treatment. The remainder of the underpayment appears to be due to the fact that CMS has incorporated the calcimimetics into the outlier pool calculation, which concerns us as well. Given the negative margins, each dollar that comes out of the program reduces the funding available to support patient care and innovation.

Thus, The Moran Company will provide additional analysis in January, we ask that both the ESRD TEP and CMS recognize that even using the options presented during the December meeting, the value of the vast majority of the adjusters that are used in the ESRD PPS today do not identify meaningful variation and should be eliminated from the payment system.

II. Low Volume Payment Adjuster Reforms

KCP is pleased that the ESRD TEP is reviewing the low volume payment adjustment and taking into account stakeholder concerns. As the review continues, KCP recommends that the ESRD TEP take into account MedPAC's concern about the overlapping nature of the low-volume and rural adjusters. In a series of 2019 meetings, the Commission reviewed an "illustrative example" of a single low-volume and isolated (LVI) facility adjuster that would better target payments. KCP conceptually supports such an approach, as we have indicated in our previous comment letters on the ESRD PPS. We believe that reviewing the MedPAC work would be a fruitful path for the ESRD TEP to follow, because it supports the intent of the Congress to address the higher costs low volume facilities face and addresses the concerns about the rural adjuster not being appropriately targeted.

III. Accounting for the Cost of Innovation

In addition to the adjusters, KCP encourages the ESRD TEP to take up the suggestions of many patients in the kidney care community to find ways to promote innovation in kidney care. While the ESRD TEP focused on what MedPAC calls the "oral-only" Transitional Drug Add-On Payment Adjustment (TDAPA), it is important that the ESRD PPS TEP and CMS recognize the critical importance of the TDAPA for other innovative products as well, both those that would fit within an existing functional category and those that would not. A long-term sustainable pathway is also necessary for these products. We share the concerns of many in the community that the chronic underfunding of the benefit discourages the long-term adoption of truly innovative products. Given the scope of the ESRD TEP and review of these transitional add-ons, we encourage the ESRD TEP to consider innovative payment policies more broadly to protect access to these treatment options for patients.

In terms of the specific discussion around the application of TDAPA to calcimimetics and the post-TDAPA period, KCP appreciates that the ESRD TEP and CMS are consulting the community through this process before simply adding the drugs to the bundle. Again, The Moran Company is reviewing the specific options presented and we will forward those analyses to you in early January. However, we do think it is important that as the ESRD TEP and CMS consider policies in this area that you avoid repeating the problems identified with the case-mix adjusters that exist today. We are deeply troubled that there could be a patient-level adjuster linked to reimbursement dollars added to the ESRD PPS for these products that would not accurately pay for the product that the patients receive. We ask CMS to share how it plans to value these products, which is an important consideration in determining how they will be added to the bundle and the dollars allocated before any proposal is made through rulemaking.

IV. Conclusions

Again, KCP appreciates the work that Acumen and CMS are doing to address suggestions and concerns that we and others in the community have raised during the commenting process. The analytical underpinning of the system is critically important and we will provide additional thoughts in that regard in the coming weeks; however, it is also important to keep the broader principals of a bundled payment system at the forefront of any discussion, as well as to balance the benefits of attaining incremental precision against the substantial costs of increasing documentation and data submission requirements. At the end of the day, we ask Acumen and CMS to prioritize ensuring that the bundled rate adequately covers the cost of providing care to patients and incentivizes over the long-term the use truly innovative products. KCP believes that taking this approach will result in better outcomes for patients and reductions in overall Medicare spending by reducing hospitalizations and other costly services outside of the ESRD PPS. Please do not hesitate to contact Kathy Lester at klester@lesterhealthlaw.com or 202-534-1773 if you have any questions or would like to discussion our comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Butler', with a stylized flourish extending to the right.

John Butler
Chairman

cc: Jason Bennett, Acting Director Chronic Care Policy Group
Jeanette Kranacs, Deputy Director Chronic Care Policy Group
Abigail Ryan, Deputy Director Division of Chronic Care Management
Lindsey Pulliam
Michelle Cruse

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
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