



March 2, 2018

Demetrios Kouzoukas  
Principal Deputy Administrator and Director  
Center for Medicare  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20510

**Re: “CMS-2017-0163 -- “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter” and “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model”**

Dear Mr. Kouzoukas,

I am writing on behalf of Kidney Care Partners (KCP) to provide comments on the “Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter” (Call Letter). 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 End-Stage Renal Disease (ESRD).<sup>1</sup>

KCP strongly supports providing beneficiaries living with kidney failure with the ability to select the type of health insurance they believe will best meet their needs. We are pleased that all ESRD patients will have access to MA plans, which will promote coordinated care that may result in better management of kidney failure and related diseases and disorders. It is important to ensure access to MA plans by providing them with full funding. As described in detail below, KCP supports the dialysis-only ESRD USPPC growth percentage for CY 2019, the ESRD Normalization Factor trend, and the proposed CKD coefficient. We are concerned, however, with the lack of guidance around calcimimetics, the recalibration of the ESRD risk adjusters, and the payment year blend of Risk Adjustment Processing System (RAPS) to Encounter Data System (EDS).

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<sup>1</sup> A list of KCP members is provided in Appendix A.

**I. KCP supports the dialysis-only ESRD USPCC growth percentage for CY 2019**

KCP supports the projected 5.07 percent increase in the dialysis-only ESRD USPCC growth percentage for CY 2019.<sup>2</sup> This projection more accurately reflects the overall dialysis fee schedule cost trends and is closer to trends in the ESRD Seamless Care Organization (ESCO) demonstration program.

**II. KCP supports the ESRD normalization factor trend.**

The normalization factor is critically important to ensuring adequate payments for ESRD patients in MA plans. We are pleased that the CY 2019 normalization factor addresses concerns we raised during last year's comment period and that CMS resolved in the final announcement. As noted below, problems with the recalibration of the risk adjustment model should be addressed to avoid the negative impact on the normalization factor as well.

**III. KCP is deeply concerned that the Call Letter does not address the shift of calcimimetics from Part D to Part B.**

With the introduction of Parasvib<sup>TM</sup> January 1, 2018, CMS under the ESRD PPS now pays for this new intravenous calcimimetic and the oral calcimimetic Sensipar® under the PPS with a transitional drug add-on payment adjustment. While KCP appreciates the informal guidance provided last year, we are disappointed that no formal notice has been published with respect to the applicability of this change in MA. Even more concerning is that the Call Letter does not acknowledge this change in coverage. Approximately one third of ESRD patients rely upon calcimimetics. The cost of these drugs is substantial, as is its importance to the patients who rely upon them.

We believe it is critically important that the MA policies reflect this change in national coverage of Sensipar®. CMS requires MA plans to pay for the basic benefits offered under Medicare Parts A and B,<sup>3</sup> and current law already requires CMS to adjust MA capitation rates or make other adjustments to account for changes in covered items and services when the change represents a "significant cost."<sup>4</sup> In the CY 2018 ESRD PPS Final Rule, CMS confirmed that with the introduction of an intravenous calcimimetic, oral calcimimetics, which until January 1, 2018, were covered under Medicare Part D, would be covered under Part B, considered part of the ESRD PPS and paid for using a two-year transition period.<sup>5</sup> While KCP has requested formal guidance for MA plans on numerous occasions, we have not seen anything published to date.

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<sup>2</sup>See Call Letter 7 (Feb. 1, 2018).

<sup>3</sup>42 C.F.R. § 422.504(a)(3)(i)

<sup>4</sup>See, 42 U.S.C. § 1395w-23(c)(7); 42 C.F.R. § 422.308(g); 42 C.F.R. § 422.109.

<sup>5</sup>82 *Fed. Reg.* 50738 (Nov. 1, 2017).

Without such guidance, plans are not indicating how they will incorporate these drugs into their reimbursement structures, which could create serious access issues for patients. While we appreciate that over time the expenditures on calcimimetics will be incorporated into the MA benchmark calculations, the lag time will create serious problems because the current rates are simply too low for any costly item to be incorporated.

We are also particularly concerned that C-SNPs will be penalized unless CMS recognizes the shift from Part D to Part B. C-SNPs have not had responsibility for covering Part D drugs. Having the calcimimetics shift into Part B will require them to cover a costly new item without funding for it. CMS needs to address this substantial change in responsibility for the C-SNP plans to ensure that patients who require these drugs continue to be able to do so without placing the C-SNP in an untenable position.

The kidney care community would welcome the opportunity to work with CMS to develop an appropriate adjustment or mechanism to ensure that the lag time inherent in the MA benchmark calculation does not result in access problems for patients who need these drugs.

**IV. KCP recommends that CMS revisit the recalibration of the ESRD Risk Adjustment Model and limit any one-year change to avoid substantial disruption in rates.**

KCP appreciates the need to make sure that payment models are based upon the most recent data available and are adjusted in line with such data. Thus, in principle, we support the concept of recalibrating the ESRD Risk Adjustment Model from time-to-time. However, the proposed recalibration does not appear to be neutral relative to the 2012 model. This means that the risk scores will be inappropriately lowered, reducing payments for MA ESRD enrollees. In turn, the normalization factor will be affected and further inappropriately lower the payment. Thus, CMS should revisit the recalibration of the ESRD Risk Adjustment Model and address this problem before implementing any changes. Also, as described below, we believe that there should be mechanisms that allow for appropriate changes that occur to the model – especially ones that lead to dramatically different adjustments – be moderated to allow for an appropriate glide-path that does not shock the delivery system in a single year.

First, based on analyses from KCP members, we believe one reason for the dramatic change in the risk scores is that the 2019 model does not achieving risk score neutrality when compared to the 2012 model. There is a difference in the dialysis, transplant, and post-graph risk scores when examined separately. The lack of neutrality means that the population of ESRD MA ESRD beneficiaries will not mirror the fee-for-service population. Therefore, we ask that CMS revisit the proposed model and validate its use for the MA-Eligible ESRD beneficiary population.

Given the need to recalibrate the model, we believe the proposed changes<sup>6</sup> are well-intended, but unfortunately reduce the beneficiary age and gender risk scores by nearly 20 percent. Because this risk score represents roughly two-thirds of the total risk score, the proposed change means that the average plan ESRD dialysis risk score will decrease substantially. The entire kidney care community is deeply concerned that such a dramatic change will result in plans reducing the benefits to a population for which they are critically important. To avoid this negative result for beneficiaries, we ask that CMS reconsider implementing the entire recalibration change to the risk scores and instead spread them out over a period of three years. Phase-ins, as you are aware, are common to allow entities to adjust to extreme changes in payment rates. The time will allow plans to work to find ways to maintain beneficiaries' services instead of having them substantially reduced or eliminated all at once.

In addition, KCP believes it is important to ensure that payment policies incentivize transplant services. The current model is undervaluing the costs for organ procurement for living and deceased donation. Transplant is the best treatment option for many beneficiaries with ESRD. The recalibration provides CMS with an opportunity to address the long-standing problem that the current policies lead to under-reimbursement. Therefore, we ask CMS to revise the ESRD Kidney Transplant CMS-HCC Model relative factors for transplant beneficiaries.

The chart on page 81 of the Call Letter outlines the problem.

**Table V-8. ESRD Kidney Transplant CMS-HCC Model Relative Factors for Transplant Beneficiaries**

|                                  | <b>Beneficiaries</b> | <b>Kidney Transplant <i>Actual Dollars</i></b> | <b>Kidney Transplant <i>Relative Risk Factor</i></b> |
|----------------------------------|----------------------|--|--|
| Month 1                          | 9,606                | \$41,260.76                                    | 6.030  |
| Months 2 and 3                   | 18,651               | 6,126.29                                       | 0.895  |
| <b>Total (Actual Months 1-3)</b> |                      | <b>\$53,493.60</b>                             |  |

**NOTES:**

1. Kidney transplant is identified by MS-DRG 652.
2. The transplant month payments were computed by aggregating the costs for each of the three monthly payments.
3. The transplant factor is calculated in this manner: (kidney transplant month's dollars/Dialysis Denominator) ×12. The CMS ESRD Dialysis Denominator value used was \$82,113.76.

**SOURCE:** RTI International analysis of 2014/2015 Medicare 100% ESRD claims and enrollment data

First, the chart shows that during the first month, plan reimbursement would be based only on MS-DRG 652, which is a kidney-only transplant code. The limitation of the month one to this code ignores the reality that many ESRD beneficiaries receive another organ transplant at the same time as they receive a kidney transplant. The most common

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<sup>6</sup> Call Letter at 30-34.

of the multi-organ transplants is kidney-pancreas, under MS-DRG 008. Multiple organ transplants can more than double to cost of a transplant. The Call Letter policies should account for such transplants. Therefore, we request that the transplant factors be modified to include all types of kidney-related transplant. This change would then necessitate an increase in the risk factor to cover the cost of the more expensive multi-organ transplants. It is important that the payment system not disadvantage plans that are appropriately following physicians' decisions to perform multi-organ transplants for ESRD patients, when medically necessary and appropriate.

Second, the current model does not align with the fee-for-service policy that pays for the organ acquisition cost separately.<sup>7</sup> As CMS has consistently acknowledged, failing to reimburse to cost of acquiring an organ creates an enormous disincentive for providing a transplant. This is because the organ acquisition cost substantially increases the cost of the transplant. Using 2014 data, Milliman has estimated that the cost to procure a kidney on average is \$84,000.<sup>8</sup> Just as it does under traditional Medicare, CMS should reimburse MA plans separately for the cost of acquiring organs. We recommend that it do so by adding the amounts to the Kidney Transplant Actual Dollars and Kidney Transplant Relative Risk Factor calculation.

Third, there are several unanswered questions as to how the costs of dialysis during the month of transplant are factored in when a patient is shifting from dialysis to the transplant. Similarly, it is unclear how complications that may occur are factored in. The system should also account for costs related to post-surgical complications and ensure they are reimbursed. Post-surgical costs for physician services are covered in the fee-for-service program for an unlimited number of days if a complication was in connection with the donation surgery.

In sum, we recommend address these issues to ensure that payment policies appropriately incentivize transplant services.

#### **V. KCP recommends retaining the 2018 payment year blend of Risk Adjustment Processing System (RAPS) to Encounter Data System (EDS)**

Ensuring adequate payment to MA plans, especially for specific populations like patients with kidney disease, is essential to maintaining a strong Medicare Advantage Program. The shift from the RAPS to EDS threatens payment rates, as studies have shown. For example, when Milliman compared PY 2016 risk scores using RAPS versus using EDS, it "found that the median percentage difference between PY 2016 risk scores based on RAPS and the EDS-based risk scores is 4.0%. The percentage difference is larger for special needs plans (SNPs) and smaller for general enrollment plans." It concluded that "[t]o the extent that this -4% gap persists in future years, the revenue impact will grow because the EDS-

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<sup>7</sup>See, e.g., 42 C.F.R. § 412.100.

<sup>8</sup>Milliman Research Report, "2014 U.S. Organ and Tissue Transplant Cost Estimates and Discussion" 7 (December 2014).

based risk score will make up an increasing portion of the final risk score.”<sup>9</sup> The differential appears to result from the facts that in the EDS, fewer HCCs are being captured, which leads to inaccuracies in member records.

The decrease in risk scores, lower the payment rates which may result in plans no longer being able to offer certain services to beneficiaries, especially those who require higher-cost care and could most benefit from additional services.

Thus, rather than increase the blended rate to 25/75 percent for PY 2019, we recommend that CMS maintain the PY 2018 blended rate and address the problems with the completeness and accuracy of EDS submissions. The latter could be done through CMS providing more specific guidance to plans regarding the EDS operations and data processing. Without specific guidance, plans may not be able to address errors on rejected records.

#### **VI. KCP supports using the Proposed Payment Count Model and including a Chronic Kidney Disease (CKD) 3 Risk Adjustment and Including a Coefficient for CKD in the RxHCC.**

KCP is pleased that the Call Letter proposes to include a CKD 3 risk adjustment, regardless of the model adopted. Given that CMS has calculated the CKD 3 coefficient in the absence of any condition count model, we urge CMS to move forward and apply this CKD 3 coefficient in PY 2019 regardless of which path CMS ultimately takes in phasing in condition counts.

In terms of the request for recommendations on the condition count two models, KCP prefers the use of the proposed Payment Condition Count Model. We are concerned that even though CKD 3 would be counted in the All Conditions Count Model, not having a coefficient negates the intended purpose of ensuring that medically complex-higher cost beneficiaries are not adversely selected, and plans are properly compensated for their care. In addition, KCP agrees with CMS that the Payment Condition Count Model better serves the intent of accounting for beneficiaries with multiple chronic conditions that contribute to significantly to higher spending. As noted in our previous letters, KCP supports providing a coefficient for CKD 3 as this is a clinically meaningful condition, indicative of increased costs, and definitively diagnosed based on lab values.

We understand the concern that CMS is unable to distinguish between CKD 3a and 3b due to lack of specificity in the ICD-CM codes. We agree that if such information were available, CMS would likely be able to more accurately predict costs. However, even in an overall manner, having CKD 3 still is associated with increased costs and it is appropriate to include it in the risk adjustment model.

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<sup>9</sup>Milliman, “Impact of the transition from RAPS to EDS on Medicare Advantage risk scores” (Jan 2017).

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Similarly, we believe that the RxHCC should also include a coefficient for CKD 3 to align with the addition of CKD 3 to the HCC risk adjustment. Patients with CKD 3 also have higher prescription drug costs than the average Medicare beneficiary. In previous years of the risk adjustment model a coefficient for CKD 3 was included in both the HCC and HCC Rx models, which KCP supported. We ask that the final letter include such a coefficient again.

## **V. Conclusion**

Thank you again for providing us with the opportunity to comment on the Call Letter. Please do not hesitate to contact Kathy Lester at [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) or (202) 534-1773 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "AR Nissenson, MD". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Allen R. Nissenson, MD  
Chairman  
Kidney Care Partners

**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  
Baxter  
Board of Nephrology Examiners and Technology  
Centers for Dialysis Care  
DaVita Healthcare Partners Inc.  
Dialysis Clinic, Inc.  
Dialysis Patient Citizens  
Fresenius Medical Care North America  
Fresenius Medicare Care Renal Therapies Group  
Greenfield Health Systems  
Keryx Biopharmaceuticals, Inc.  
Kidney Care Council  
National Kidney Foundation  
National Renal Administrators Association  
Northwest Kidney Centers  
Nephrology Nursing Certification Commission  
NxStage Medical, Inc.  
Renal Physicians Association  
Renal Support Network  
Rogosin Institute  
Sanofi  
Satellite Health Care  
U.S. Renal Care