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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 CMS-HCC Risk Adjustment Model and 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

Dear Mr. Kouzoukas,

The National Kidney Foundation appreciates the opportunity to comment 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. The National Kidney Foundation is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention and treatment of kidney disease in the US. In addition, the National Kidney Foundation has provided evidence-based clinical practice guidelines for all stages of chronic kidney disease (CKD), including transplantation since 1997 through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI).

### **Changes in the Medicare Part C Payment Methodology**

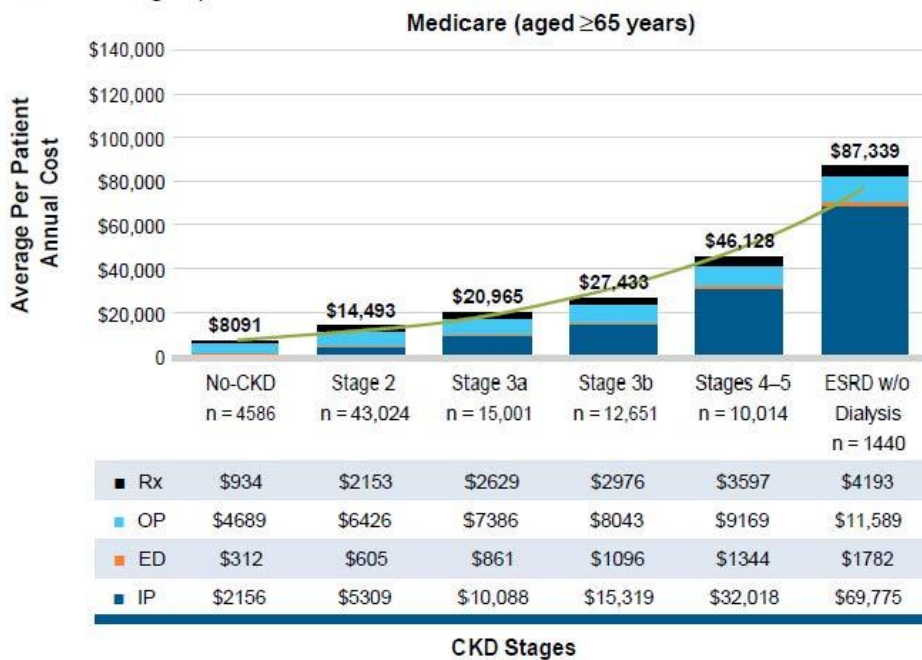
#### Risk Adjustment Model

The National Kidney Foundation strongly supports the proposal to move forward with including a coefficient for CKD 3 to the Hierarchical Condition Category (HCC) risk adjustment model, beginning in 2019. We appreciate that CMS has reevaluated and reconsidered the inclusion of CKD 3, which was removed entirely from the model in 2016. As we have previously advocated, risk adjustment for CKD 3 is clinically meaningful, indicative of increased costs and supports appropriate diagnosis and monitoring of progression and as such is appropriate to include in the risk adjustment model. CKD can be diagnosed

based on laboratory data typically involving a blood test of serum creatinine used to calculate an estimated glomerular filtration rate (eGFR), which is part of a basic metabolic panel and reported by most laboratories in the U.S, and the urine albumin to creatinine ratio (ACR). The KDIGO and KDOQI guidelines recommend diagnosis of CKD based on two tests of both eGFR and ACR conducted at least 90 days apart. People at highest risk for CKD are those with diabetes and/or hypertension and the National Kidney Foundation recommends testing for CKD at least annually in this population as well as to monitor progression in those with a diagnosis of CKD.

A recent study evaluated the costs of CKD in Medicare patients by stage including CKD 3a and 3b. Both 3a and 3b were indicative of significantly higher spending when compared to Medicare beneficiaries without CKD.<sup>1</sup>

**B. Medicare group.**



CKD indicates chronic kidney disease; ED, emergency department; ESRD, end-stage renal disease; IP, inpatient; OP, outpatient; Rx, prescription.  
 All Comparisons  $P < .0001$ . Total Costs and costs by service category have been rounded to the nearest dollar.

<sup>1</sup> Golestaneh, Ladan All-Cause Costs Increase Exponentially with Increased Chronic Kidney Disease Stage, AJMC, Vol. 23; No. 10, Sup. June 2017.

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While it is unfortunate that ICD-10CM does not differentiate between CKD 3a and 3b or ranges of ACR, adjusting for CKD 3 overall remains both clinically meaningful and indicative of expected increased costs. ACR is not necessary to determine stage of CKD but is vitally important to determining risk of progression and cardiovascular events. Recently, the National Kidney Foundation in partnership with the American Society of Clinical Pathology, other leading clinical laboratory societies and leading clinical laboratories introduced a “kidney profile” test in the U.S. that includes both the eGFR and ACR. The kidney profile will allow clinicians to easily add ACR when ordering a basic metabolic panel or testing for eGFR. This is likely to increase the use and recording of ACR by clinicians and will improve the ease of diagnosis and monitoring in CKD.<sup>2</sup> Should there be future refinements for CKD in to ICD10-CM to distinguish between stage 3a and 3b and level of ACR (and NKF recommends there should be such a refinement) this would provide CMS with additional information to evaluate the impact of tailoring the model for CKD risk adjustment to distinguish costs between CKD 3a and 3b and also potentially further refine outcomes based on category of ACR (normal to mildly increased (<30 mg/g), moderately increased (30-299 mg/g), severely increased (>300 mg/g). Refinement of ICD10-CM to include ranges of ACR could also help evaluate the appropriateness of including earlier CKD stages when ACR is elevated, which is associated with increased cardiovascular risk.

The National Kidney Foundation also believes that using the proposed Payment Condition Count Model is more appropriate than the All Condition Count Model. The All Condition Count Model would nullify in many cases, not just for CKD, the adjustment for clinically meaningful conditions that predict higher costs and protect sicker beneficiaries from adverse selection. The Payment Condition Count Model maintains the meaningfulness of the risk adjustment model while also accounting for beneficiaries who have multiple chronic conditions. Therefore, we support the CMS proposal to move forward with phasing in the Payment Condition Count Model beginning in 2019. Regardless, as to whether CMS ultimately decides to delay the phase-in of the new model, we recommend that the agency still proceed with fully including CKD 3 in the risk adjustment model in 2019 as it was evaluated independently from the condition count models. Conversations the National Kidney Foundation has had with commercial payers operating Medicare Advantage plans have indicated that CMS removal of CKD 3 from the risk adjustment model in previous years led to a misperception that CKD 3 may not be clinically meaningful or predictive of costs. We believe this may have slowed improvements in diagnosis over the past few years.

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<sup>2</sup> <https://www.kidney.org/news/national-kidney-foundation-american-society-clinical-pathology-leading-laboratories-and>

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## **ESRD Model Recalibration**

The National Kidney Foundation appreciates CMS updating the ESRD model in advance of implementing legislative changes from the 21<sup>st</sup> Century Cures Act that will allow ESRD beneficiaries the ability to enroll in MA plans. However, updating the model to use most recent years of data will result in a substantial decrease in payments to plans via lower risk scores for most ESRD beneficiaries. We are concerned that plans will raise premiums and cost-sharing to off-set this reduction or result in a reduction of benefits. We believe that this substantial of a change to the payment rates needs to be phased in over three-years to give plans time to make adjustments that won't result in substantial increases in costs to beneficiaries.

Additionally, as CMS is recalibrating ESRD rates we encourage the agency to also revisit the HCC risk adjustment model for ESRD kidney transplant beneficiaries. We believe this model is undervaluing the costs associated with transplantation. We have heard concerns from transplant social workers that in some locations there are already few and sometimes only one transplant center in network within the geographical region making access to transplant more difficult for beneficiaries. Appropriate compensation for the costs of transplant are necessary to ensuring beneficiaries with kidney failure have better access to this treatment, which is as close to a cure for ESRD as is currently available. Specifically, we recommend that CMS consider the costs of multi-organ transplants as 789 kidney transplant recipients last year also received a pancreas transplant.<sup>3</sup> CMS appears to only base risk adjustment for the month of surgery on the MS-DRG for kidney transplant alone. It is also unclear how the costs of dialysis during the month of transplantation are also factored into the model.

In addition, while we recognize that beginning in 2021 CMS will pay for organ acquisition costs under Medicare Fee-for-service (FFS) as a result of the 21<sup>st</sup> Century Cures Act, until then CMS should reimburse MA plans separately for organ acquisition costs as it does in Medicare FFS. We believe the current model is undervaluing the costs for organ procurement for living and deceased donation. The costs of caring for the living donor after transplant also need to be accounted for in the acquisition cost as they are in FFS and any costs necessary related to post-surgical complications need to be accounted for and reimbursed as well. Post-surgical costs for physician services are covered in FFS for an unlimited number of days if a complication was in connection with the donation surgery.<sup>4</sup> The National Kidney Foundation urges CMS to take this opportunity to revisit the calculations for kidney transplant beneficiaries and ensure the model does not continue to under reimburse for this gold-standard in ESRD treatment.

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<sup>3</sup> United Network for Organ Sharing Transplant Trends 2017, [https://unos.org/data/transplant-trends/#transplants\\_by\\_organ\\_type+year+2017](https://unos.org/data/transplant-trends/#transplants_by_organ_type+year+2017), accessed February 26, 2018.

<sup>4</sup> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R471pr1.pdf>

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## **Changes in the Payment Methodology for Medicare Part D**

### RxHCC Model and CKD

The National Kidney Foundation questions why a coefficient for CKD 3 was not included in Rx HCC risk adjustment model to align with the addition of CKD 3 to the HCC risk adjustment. Medicare beneficiaries with CKD 3 have higher prescription drug costs than the average Medicare beneficiary as is shown in the figure on page 2 of this letter. In previous years of the risk adjustment model a coefficient for CKD 3 was included in both the HCC and HCC Rx models.

### Immunosuppressive drugs

The National Kidney Foundation appreciates CMS addressing an ongoing challenge for Medicare beneficiaries in determining Part B vs. D coverage of immunosuppressive drugs. This has been a particular challenge for beneficiaries in MAPD plans as the benefit is frequently miscategorized to Part D, which may result in higher beneficiary cost sharing for immunosuppressive drugs. However, we have questions and concerns about the proposal to use the MARx to capture when a Medicare covered transplant has occurred.

Often, Medicare coverage is applied for after the transplant and coverage can be retroactive for 12 months. If pharmacies have to rely on MARx to determine that it was a Medicare covered transplant that information may not be available. Additionally, if the patient has a primary commercial insurance and they've met their deductible, again, Medicare would not have paid for any part of the transplant even though Medicare coverage might be in place.

Additionally, while under this proposal Part D plans may document the basis for their determinations to cover immunosuppressants and make such documentation available for audit, patients can and do change Part D plans annually, how will that information be transferred from one plan to the next? If that information can't be transferred and provided to the patient's new Part D plan at the beginning of the year, then patient access to immunosuppressive drugs would be delayed. Patients can also change MA plans annually and there will likely be no history indicating Part B vs. Part D coverage when they do. Patients also may use multiple pharmacies which could also confuse the process. Also, if a beneficiary receives a notice that their coverage benefit for immunosuppressive drugs has changed they need to simultaneously be notified how to access their immunosuppressive drugs as a result. We are concerned without clear guidance to beneficiaries, confusion on accessing immunosuppressive drugs could cause delays in obtaining them putting the transplanted organ at risk of rejection.

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The National Kidney Foundation recognizes a need to address this benefit confusion as improper benefit categorization can cause transplant recipients patients to accelerate towards the coverage gap more quickly than they otherwise should causing them to have difficulty affording all their prescribed medications. It is vitally important that Part B vs. D coverage be clearly established from the time the patient is transplanted and communicated immediately to MA and Part D plans and annually as recipients change health plans. The National Kidney Foundation welcomes the opportunity to further discuss a solution with CMS on benefit category confusion for immunosuppressive drugs.

The National Kidney Foundation also appreciates that the agency is continuing its policy of maintaining protected class status for immunosuppressive drugs when covered under Part D for organ transplant recipients. This policy is critical to ensuring transplant recipients have access to the necessary combinations of medications that best meet their individual needs to balance appropriate immune suppression with the significant side-effects of such medications.

#### Coverage of calcimimetics in Medicare Part B vs D.

The National Kidney Foundation urges CMS to include formal guidance and appropriate payment to MA plans for the change in status of oral calcimimetics Sensipar® (cinacalcet) from Part B to Part D and the introduction of Parsabiv® (etelcalcitide) an IV calcimimetic. Both medications are paid for under Medicare Part B as part of the of ESRD prospective payment system under the transitional drug add-on payment adjuster (TDAPA) effective January 1, 2018. Ensuring that appropriate compensation is made to MA plans for this change in policy is critical to ensuring ESRD patient access to these medications used to treat secondary hyperparathyroidism.

#### Vaccines

The National Kidney Foundation appreciates CMS recognition on the importance of vaccines including those that help prevent influenza and pneumonia. We encourage CMS to consider additional regulatory oversight to ensure that Part D plans are not just encouraged but required to cover vaccines with no coinsurance or by placing them on the formulary under the lowest cost-sharing tier. This policy change will protect Medicare's most vulnerable patients from these illnesses that can be life-threatening and result in increased Medicare spending. Individuals with CKD and those who have a kidney transplant and are immunosuppressed are particularly susceptible to these illnesses.

#### Specialty Tier Threshold

The National Kidney Foundation is concerned with the continued low threshold for drugs that can be placed on a specialty tier. With the rising cost of prescription drugs and growing number of high-cost

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specialty drugs this threshold is not keeping up with inflation. We believe the specialty tier threshold needs to be significantly increased to account for the cost of truly specialized medications otherwise beneficiaries with chronic conditions will continue to be disadvantaged by the policy. For example, a number of commonly prescribed immunosuppressive drugs that require no special administration or handling are frequently placed on specialty tiers under Part D. The low threshold contributes to the artificial categorization of medications as specialty and disadvantages beneficiaries who are trying to access vital medications to keep themselves healthy, out of the hospital, and for transplant recipients - trying to prevent organ failure. We urge CMS to revisit this policy to help beneficiaries better afford their medications.

### **Enhancements to the 2019 Star Ratings and Future Measurement Concepts**

The National Kidney Foundation is encouraged that CMS is considering future measure topics to include in the 2020 Star Ratings and plans to convene a technical expert panel (TEP) after finalization of the call letter to review the Star Ratings program. We encourage CMS to include experts in kidney disease, including patients with CKD in that TEP.

Unfortunately, CKD remains widely underdiagnosed. Over 30 million individuals have CKD yet, only 10% of them are aware they have it.<sup>5</sup> In the Medicare population CDC estimates 20% of seniors age 65-69 and half of seniors age 70 and older have CKD,<sup>6</sup> yet Medicare Fee for Service data indicates a diagnosis of 17.5% collectively for Medicare beneficiaries age 65 and over in 2015.<sup>7</sup> Individuals with diabetes and hypertension are at highest risk for CKD and should be evaluated using both an eGFR and ACR annually. However, in the Medicare population, only 40.5% of beneficiaries with known diabetes had urine albumin testing, compared to a paltry 6% of beneficiaries with known hypertension. Medicare beneficiaries with a combined diagnosis of diabetes, hypertension, and CKD were tested less than half the time for urine albumin, illustrating a significant gap in clinicians following progression of CKD even

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<sup>5</sup>Centers for Disease Control and Prevention, National Center for Disease Prevention and Health Promotion, Division of Diabetes Translation, CKD Surveillance Project, data from the 2011–2014 National Health and Nutrition Examination Survey and the CKD Epidemiology Collaboration (CKD-EPI) equation. Published online June 2017 at [https://www.cdc.gov/diabetes/pubs/pdf/kidney\\_factsheet.pdf](https://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf).

<sup>6</sup>Centers for Disease Control and Prevention, National Center for Disease Prevention and Health Promotion, Division of Diabetes Translation, CKD Surveillance Project, Crude Prevalence of CKD stages 1-4 by Age data from the 2011–2014 National Health and Nutrition Examination Survey published online at <https://nccd.cdc.gov/ckd/detail.aspx?Qnum=Q9#refreshPosition>, accessed February 26, 2018.

<sup>7</sup>Centers for Medicare & Medicaid Services Chronic Conditions Prevalent State Report accessed online [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC\\_Main.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CC_Main.html), February 26, 2018.

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after it has been diagnosed.<sup>8</sup> While we expect increases in urine albumin testing to occur as a result of labs implementing the aforementioned kidney profile test, we believe a quality measure will still be necessary to further improve the gap in identifying CKD early and monitoring disease progression. Unfortunately, the current star ratings measure for Diabetes: Kidney Disease Monitoring can be met without annual testing for CKD. This is problematic for multiple reasons. First, as long as a person with diabetes has been prescribed an angiotensin-converting enzyme (ACEi) inhibitors or angiotensin II receptor blockers (ARB) or have past documented evidence of having CKD they never have to be tested. However, CKD is a progressive disease and needs to be monitored at least annually. CKD can progress even in individuals who have been prescribed an ACEi or ARB. While ACEi or ARB has been found to delay progression of CKD a prescription does not indicate that the patient is taking the medication as prescribed and it is not the only intervention necessary to protect kidney health. Additionally, some cases CKD will progress faster than others even for those taking an ACEi or an ARB. Assessment of eGFR and ACR provides helpful information to clinicians and to payers to allow them to risk stratify patients and more accurately target treatments and interventions based on disease severity and risk of progression to ESRD. Lastly, performance among health plans for this measure is high as CMS has indicated in previous years MA Advanced Notice and Call Letter. High performance among health plans on this measure has been interpreted and publicized by payers as having high performance in properly assessing for CKD. The National Kidney Foundation calls on CMS to work with NCQA to adapt this measure to more appropriately reflect guideline supported testing for CKD for people with diabetes and to include individuals in the measure who have hypertension, regardless of diabetes status. The Indian Health Services has a measure for CKD assessment in people with diabetes that requires annual assessment of eGFR and ACR and could serve as a model for updating or replacing the current Diabetes: Kidney Disease Monitoring measure used in the Star Ratings.

In addition, the National Kidney Foundation recommends a new measure be added to the Star Ratings, ESRD Optimal Starts (NQF Endorsed 2594). This measure evaluates appropriate transitions of care for individuals that do progress to ESRD and was developed by the Permanente Federation. The measure encourages earlier conversations and advanced preparation for renal replacement therapy options. A little over a third of patients were cared for by a nephrologist for a minimum of 12 months before their kidneys failed leaving little opportunity for most patients to receive education about their renal replacement therapy options and participate in shared in decision making about their treatment.<sup>9</sup>

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<sup>8</sup> United States Renal Data System. 2017 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2017.

<sup>9</sup> Ibid



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In addition, 80% of patients start hemodialysis with a tunneled catheter making them more susceptible to infection instead of a permanent vascular access, such as an AV fistula.<sup>10</sup> The ESRD Optimal Starts measure would encourage plans to identify patients approaching ESRD and take measures to ensure they are engaging with nephrologists prior to kidney failure. The measure would also help to facilitate earlier conversations about transplant and dialysis options - including home dialysis and advanced vascular access placement for those that choose dialysis. This would not only improve outcomes for patients, but it's likely to generate savings to the plans by reducing multiple procedures and hospitalizations that often occur during the first 90 days that patients start dialysis. We urge CMS to incorporate the ESRD Optimal Starts measure in the MA star ratings.

The National Kidney Foundation appreciates the opportunity to comment on the CY 2019 proposed changes to the Medicare Advantage and Part D Advanced Notice and Call Letter. Please contact Tonya Saffer, Senior Health Policy Director at [tonya.saffer@kidney.org](mailto:tonya.saffer@kidney.org) or 202.244.7900 x 717 with any questions.

Sincerely,

*Kevin Longino*

Kevin Longino  
CEO  
Kidney Transplant Patient

*Michael Choi*

Michael Choi, MD  
President

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<sup>10</sup> Ibid