National Kidney Foundation®

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Demetrios Kouzoukas
Principal Deputy Administrator and Director, Center for Medicare
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Jennifer Wuggazer Lazio, F.S.A., M.A.A.A.
Director, Parts C and D Actuarial Group
Office of the Actuary
600 W. Santa Ana Blvd.
Santa Ana, CA 92701

March 6, 2020

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies – Part II

Dear Principal Deputy Administrator Kouzoukas and Director Wuggazer,

The National Kidney Foundation appreciates the opportunity to offer comments on Part II of the Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. We offer the following comments with the goal of enabling CMS to best serve patients who are at risk of chronic kidney disease (CKD), diagnosed with CKD, and those who have transitioned to end-stage renal disease (ESRD) through the MA program. Our comments will address several issues raised in the proposed rule, "Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly." Though we acknowledge that these issues are out of scope of the Advance Notice, we believe it is critically important that they be addressed prior to the due date for MA plan bids, at which time decisions about benefit structure that will impact patients will already have been made.

The National Kidney Foundation (NKF) is the largest, most comprehensive and longstanding, patient centric organization dedicated to the awareness, prevention, and treatment of kidney disease in the U.S. 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).

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NKF is committed to both expanding choices for kidney patients as they navigate the health system and providing information that enables patients to make the best decisions for their unique circumstances. As such, NKF thanks CMS for its efforts to implement the statutory provisions of the 21st Century Cures Act that allow end-stage renal disease beneficiaries to enroll in MA plans.

Advance Notice Section D. ESRD Rates

NKF shares the concerns of numerous other stakeholder organizations that the ESRD benchmark is inadequate to cover the costs associated with ESRD beneficiaries due to the $6,300 difference between the FFS out-of-pocket expenditures and the MA maximum-out-of-pocket (MOOP) limit.[1] We are concerned that the current ESRD reimbursement is not sufficient to prevent premium increases across MA plans and will limit patients' ability to benefit from supplemental benefits and care coordination services that are especially valuable for kidney patients. We acknowledge that CMS has proposed enabling MA plans to increase the MOOP in order to accommodate the higher costs of ESRD beneficiaries. However, the MOOP limit is an essential patient protection and one of the advantages to patients of enrolling in an MA plan. Accordingly, passing the costs of ESRD beneficiaries on to all MA beneficiaries, including ESRD beneficiaries, is not an appropriate solution. We encourage CMS to look to alternative approaches to fully accounting for the $6,300 differential between the FFS OOP and the MA MOOP.

NKF additionally supports CMS' consideration of whether setting the ESRD rates at the metropolitan area may achieve more accurate payment for ESRD beneficiaries. We understand that there is wide variation in the expenditures for ESRD beneficiaries within states.[2] We encourage CMS to evaluate whether setting the ESRD benchmark at the level of a smaller geographic area could enable MA plans to better target their offerings to the local patient population.

Advance Notice Section G. CMS-HCC Risk Adjustment Model for CY 2021

NKF appreciates the inclusion of CKD Stage 3 in the Hierarchical Condition Category (HCC) risk adjustment model. Like CKD 3, CKD 3a and 3b are both clinically meaningful and a driver of increased costs (Figure 1). NKF has worked closely with CDC's National Center for Health Statistics on the adoption of ICD-10CM codes to distinguish CKD3a and 3b. We encourage CMS to evaluate further tailoring the risk adjustment model to account for the different costs of CKD 3a and 3b, which are primarily driven by the higher emergency department and inpatient costs associated with CKD 3b patients.[3]

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[1] Blum, J., Hammelman, E., & Ipakchi, N. (2020, February 12). End-Stage Renal Disease and Medicare Advantage . Retrieved March 6, 2020, from https://www.healthmanagement.com/wp-content/uploads/Health-Management-Associates-ESRD-and-Medicare-Advantage-White-Paper.pdf

[2] *Ibid.*

[3] 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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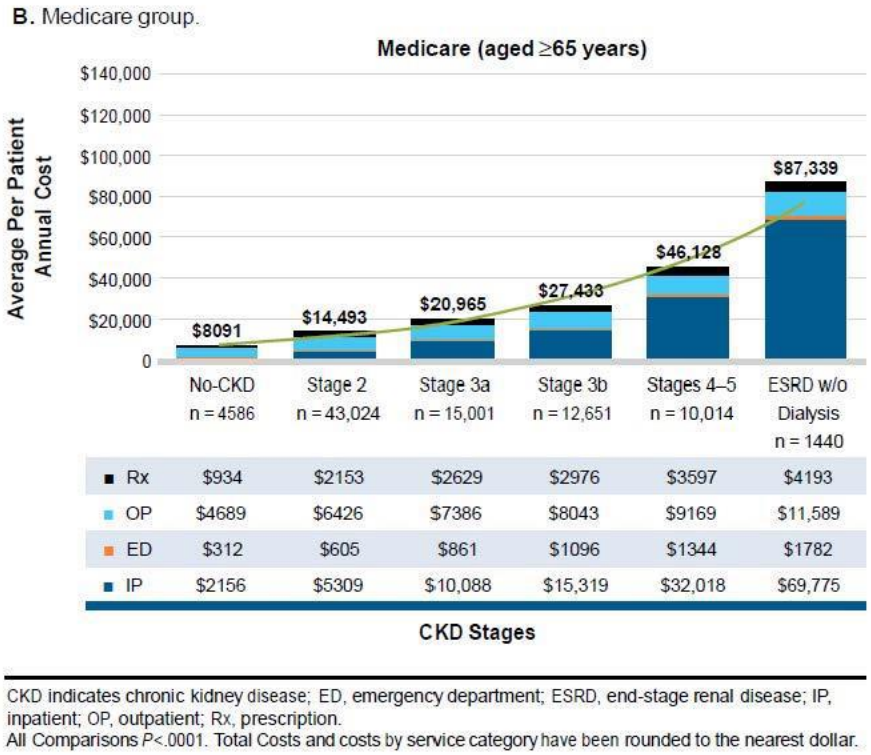
Figure 1 [4]



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.

Advance Notice Section H. ESRD Risk Adjustment Models for CY 2021

NKF encourages CMS revisit the HCC risk adjustment model for ESRD kidney transplant beneficiaries. We believe this model is undervaluing the costs associated with transplantation. 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. In 2019, 872 kidney transplant recipients also received a pancreas transplant.[5] CMS appears to only base risk adjustment for the month of surgery on the MS-DRG for kidney transplant alone (MS-DRG 652). It is also unclear how the costs of dialysis during the month of transplantation are factored into the model.

Potential New Measure Concepts

NKF thanks CMS for recognizing the need for quality measures in CKD, especially those that incentivize better screening of patients at high risk of kidney disease. As CMS notes in the Advanced Notice, the NKF-

[4] *Ibid.*
[5] https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#

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developed Kidney Health Evaluation Measure would encourage an annual kidney health evaluation in patients with diabetes based on estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (UACR), as recommended by KDOQI and the American Diabetes Association.[6,7,8] Though there are existing measures intended to drive kidney disease screening in diabetic patients, *Diabetes Care – Kidney Disease Monitoring* in the Star Ratings and Diabetes: Medical Attention for Nephropathy in MIPS, performance of eGFR and UACR remain low. NKF strongly encourages CMS to replace *Diabetes Care – Kidney Disease Monitoring* with the Kidney Health Evaluation Measure, which will galvanize critically important quality improvements in the care of diabetic patients at risk of CKD.

In addition, NKF recommends that ESRD Optimal Starts (NQF Endorsed 2594) be added to the Star Rating. This measure evaluates appropriate transitions of care for individuals that progress to ESRD and was developed by the Permanente Federation. The measure encourages earlier conversations and advanced preparation for renal replacement therapy options. In 2016, 35.4% of incident ESRD patients received little or no pre-ESRD nephrology care.[9] This leaves few opportunities for patients to receive education about their renal replacement therapy options and participate in shared in decision making about their treatment.

Eighty percent 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.[10] 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 would likely generate savings to 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.

E. Medicare Advantage (MA) and Cost Plan Network Adequacy (§§ 417.416 and 422.116)

NKF agrees with CMS that medically necessary dialysis can be accessed in different ways and that some flexibility to the time and distance standards may be appropriate. We also agree that provider consolidation may drive higher costs for patients. Our concern is that patients are not caught in the middle of the push towards either extreme: either entirely removing outpatient dialysis from the list of facilities that must meet time and distance standards rates or maintaining the time and distance standards

[6] Microvascular Complications and Foot Care: *Standards of Medical Care in Diabetes—2019*. Diabetes Care 2019;42:S124-S38.
[7] KDOQI Clinical Practice Guideline for Diabetes and CKD: 2012 Update. American Journal of Kidney Diseases 2012;60:850-86.
[8] KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease. American Journal of Kidney Diseases 2007;49:S12-S154.
[9] United States Renal Data System. 2018 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, 2018.
[10] *Ibid.*

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with no changes that empower patients to select their preferred ESRD treatment modality. We do not believe that a wholesale elimination of the time and distance standards for outpatient dialysis facilities is best for patients. Travel time to dialysis has a significant impact on patient quality of life, adherence and outcomes.[11] Conversely, in areas where plans are only able to contract with a single provider, patient choice is inappropriately limited. The following options may strike the right balance between preserving patient access to outpatient in-center dialysis and encouraging greater flexibility to plans to offer other dialysis modalities to MA patients: allowing for exceptions to the network adequacy requirements when plans are able to demonstrate a certain percentage of patients on home dialysis, if the only dialysis provider in the area is a home dialysis-only provider, or if there is only a single provider in the area in which the plan operates. NKF would welcome the opportunity to work with CMS to determine how best to meet the needs of all dialysis patients.

NKF reiterates our appreciation for the opportunity to comment on the Advance Notice. We thank CMS for its attention to the ESRD benchmark and network adequacy comments provided in these comments. NKF intends to provide additional input on the proposed rule in a separate letter. Please contact Miriam Godwin, Health Policy Analyst, at miriam.godwin@kidney.org with questions about the positions outlined herein.

Sincerely,

Kevin Longino
Kevin Longino
CEO and transplant patient

Holly Mattix Kramer
Holly Mattix Kramer, MD, MPH
President

[11] LM Moist, JL Bragg-Gresham, RL Pisoni, *et al,* "Travel time to dialysis as a predictor of health-related quality of life, adherence, and mortality: The Dialysis Outcomes and Practice Patterns Study (DOPPS)," 51 Am J Kidney Dis 641-650 (2008).