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January 25, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4180-P; Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses

Dear Administrator Verma:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule entitled "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses."

The American Kidney Fund is the nation's leading independent nonprofit organization working on behalf of the more than 30 million Americans with kidney disease. For the past half-century, AKF has existed to help people fight kidney disease and live healthier lives. We provide a complete spectrum of programs and services: top-rated education materials; free kidney disease screenings in numerous cities across the nation; clinical research funding; and need-based financial assistance enabling one in five U.S. dialysis patients to access lifesaving medical care, including dialysis and transplantation.

AKF appreciates CMS' efforts to address the rising cost of prescription drugs, and we believe policy proposals should balance the need to protect patient access to needed therapies, lower costs for beneficiaries, and ensure the financial stability of the Medicare program. However, AKF has significant concerns with CMS' proposed changes to the Medicare Part D program's six categories and classes of drugs of clinical concern (the six protected classes), which includes immunosuppressive drugs for treatment of transplant rejection. We focus our comments on CMS' proposal to establish additional exceptions to the requirement that all drugs in a protected class be included in a Part D formulary and to permit additional use of prior authorization and utilization management.

As an organization with a mission to help people fight kidney disease and live healthier lives, our comments have an emphasis on the impact the proposed changes would have on kidney transplant patients whose immunosuppressive drugs are covered through a Part D plan. We are concerned that the changes

would hinder access to clinically-appropriate medications and jeopardize the health of transplant patients and other beneficiaries with complex and chronic conditions. We ask that the agency reconsider its proposal and urge CMS to not finalize the proposed changes on the six protected classes.

CMS has proposed three new exceptions to formulary requirements for the protected classes: allowing Part D sponsors greater use of prior authorization and step therapy for protected class drugs, without distinguishing between new starts and existing therapies; permitting Part D plans to exclude from their formularies an existing protected class single-source drug or biologic product that has a new formulation, regardless of whether the older formulation remains on the market; and permitting plans to exclude from their formularies any protected class drug whose price increases beyond the rate of inflation.

While CMS does have the authority to establish exceptions to the formulary requirements for protected class drugs, current statute states that exceptions must “ensure[s] that any exception to such requirement is based upon scientific evidence and medical standards of practice.”¹ However, in the proposed rule CMS does not demonstrate that its proposed exceptions to formulary requirements is based on scientific evidence or clinical rationale. Rather, the proposed changes seem to be focused solely on cost, without proper consideration for the detrimental effects they would have on the health of patients with complex chronic conditions.

For kidney disease patients who have received a transplant, policies that create additional barriers to access for immunosuppressive drugs can have dire consequences. Transplant recipients must take immunosuppressive drugs for the remainder of the life of their transplanted organs. Without them, their bodies will reject their new organs. However, immunosuppressive drugs can have serious side effects, including nephrotoxicity (damage to the kidney caused by toxins or medication), hypertension, high cholesterol, increased risk of infections, slow wound healing, low platelets in the blood, and diarrhea.² We have talked to transplant patients who have encountered these side effects and others, including tremors/uncontrollable shaking, night sweats, blurry vision, rashes, nausea, severe headaches, and swelling and pain in their legs. Individual patients may react differently to certain drugs, and given the need to mitigate side effects while also managing the risk of organ rejection, it is imperative that transplant patients have access to the full range of immunosuppressive drugs so they can find the right regimen that works for them.

If a transplant patient on an existing stable drug regimen must contend with new prior authorization or step therapy policies, or the removal of a prescribed medication from their plan formulary, it would pose a risk to the donated kidney and the patient’s health. This would be particularly true for the many kidney transplant patients who have other chronic conditions that require medications, including drugs that are also in a protected class. For example, depressive illness is more common amongst kidney transplant patients than the general population.³ A kidney transplant patient with

¹ 42 U.S.C. § 1395w-104(b)(3)(G)(iii).

² Ekberg, Henrik, *et al.*, “Reduced Exposure to Calcineurin Inhibitors in Renal Transplantation” 357 N. Engl. J. Med. 2562, 2563 (Dec. 20, 2007).

³ Veater N.L., East L.. (2016) Exploring depression amongst kidney transplant recipients: A literature review. Journal of Renal Care 42(3),172–184.

depression works closely with their providers to ensure their medications do not interfere with each other; creating impediments within the Part D program that could disrupt their stable drug regimen puts that patient's health at risk.

CMS' concerns about overutilization within the protected classes, especially as it concerns immunosuppressive drugs, are misplaced. The stories we hear from transplant patients regarding the myriad side effects they encounter make it clear that taking immunosuppressive drugs can be a difficult experience, but it is necessary. Also, the proposed changes in this rule do not recognize the reality of how Part D plans' current use of utilization management and tier placement, combined with the availability of generics, has effectively driven greater use of lower cost options within the protected classes. For example, an analysis from Avalere shows that, on average, plans only cover 49% of available brand name immunosuppressive drugs.⁴ Among those brand name immunosuppressive drugs, plans place most of those drugs (72%) on formulary tiers that require higher beneficiary cost-sharing using coinsurance instead of co-payments.⁵ The transplant patients we talk to are overwhelmingly prescribed generic immunosuppressive drugs.

Finally, as it relates to immunosuppressive drugs and transplant patients, the proposed rule fails to recognize that donated organs are a scarce resource, and policy proposals that seek to lower program costs while limiting access to needed drug therapies will lead to increased overall cost for the Medicare program. More importantly, it endangers patient health. Reduced access to needed immunosuppressive drugs could lead to adverse health outcomes and ultimately organ rejection, which would then have the unintended consequence of increasing costs in Medicare Part A and B due to more frequent physician visits and hospitalizations and the patient going on dialysis. Per person Medicare spending on kidney transplants is \$34,780; per person Medicare spending on immunosuppressive drugs costs about \$2,300 per year, and Part D spending for kidney transplant patients is about \$6,000 per year.⁶ Comparatively, per person per year Medicare spending on a dialysis patient is more than \$89,000.⁷

Thank you for your consideration of AKF's comments and recommendations.

Sincerely,



President and CEO

⁴ "Medicare Part D's Six Protected Classes Policy: A Balanced Approach to Provide Patients Access to Medications While Allowing Powerful Tools to Control Costs," Partnership for Part D Access (2018), available at: http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf.

⁵ Ibid.

⁶ USRDS, 2018 USRDS Annual Data Report available at <https://www.usrds.org>

⁷ Ibid.

