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February 19, 2019

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

**Re: CMS-9926-P; Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020**

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 regarding the "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020."

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.

**Mid-Year Changes to Prescription Drug Formularies**

CMS proposes to allow issuers in the individual, small group, and large group markets to make certain mid-year changes to their prescription drug formulary, if permitted under applicable state law. Specifically, issuers can add a generic equivalent of a drug that becomes available on the market, and they will be permitted to remove the equivalent brand drug(s) from the formulary or move the brand drug(s) to a different cost-sharing tier.

AKF appreciates CMS' efforts to address the affordability of prescription drugs, and we support efforts to encourage the introduction and availability of generic prescription drugs, such as allowing issuers to add generic equivalent drugs to their formulary mid-year. However, there also need to be safeguards in place to ensure that patients for whom generic substitution is not medically appropriate still have access to branded drugs that are part of their stable drug regimen. We recognize

and appreciate that CMS tries to address this need for patient safeguards in the proposed rule by requiring issuers to provide enrollees with 60 days advanced notice before removing a brand drug from the formulary or moving it to a different cost-sharing tier. CMS is also requiring issuers to inform enrollees and provide them the option to request coverage of the brand drug through the appeals process or the drug exception process. However, the appeals and exception process does not guarantee access to a requested drug, and we are concerned that for a patient for whom a generic is not medically appropriate, they may still be left without access to needed medication in the middle of the plan year. This would be disruptive to their care and could jeopardize their health, particularly if they are living with a chronic condition like kidney disease or have multiple chronic conditions.

We ask that CMS reconsider this portion of its proposal and prohibit issuers from removing a brand drug from its formulary mid-year. As CMS notes in the rule, consumers often purchase a plan based on the plans' drug coverage. Prohibiting removal of a brand drug mid-year would better guarantee access to medically-necessary prescription drugs during the plan year and minimize treatment disruptions and administrative burden for patients.

### **Cost-Sharing Requirements for Generic Drugs**

CMS is proposing, subject to applicable state law, to permit group health plans, group health insurance coverage, and individual market plans that cover both a brand drug and its generic equivalent, to exclude the brand drug from being considered an essential health benefit (EHB) if the generic drug is available and medically appropriate for the enrollee. Plans who exercise this option would be required to have an exception process in place for the enrollee to request coverage of the brand drug.

AKF has concerns with this proposed change as it could have a disproportionate impact on patients who have chronic and complex health needs (such as kidney disease patients with comorbidities) and who may rely on access to a medically-necessary brand drug. As noted above, the exception process does not guarantee coverage of a drug, and for a patient who is denied coverage under the exception process, they would face much greater out-of-pocket costs because their cost-sharing spending on the drug would not count towards their annual out-of-pocket maximum. In addition, plans would be permitted to impose annual and lifetime dollar limits on the drug because it would not be considered an EHB. Because of the financial impact on patients and the effect it could have on access to medically-appropriate treatment, we recommend that CMS not finalize this proposal.

### **Cost-Sharing Requirements and Drug Manufacturers Coupons**

CMS proposes that any form of direct manufacturer cost-sharing support is not required to be counted toward the annual limit on out-of-pocket costs if the support is for specific brand drugs that have a generic equivalent.

We reiterate our support for the introduction and availability of generic drugs, and we support the use of generic drugs when medically-appropriate. However, effective drug regimens depend on how the individual patient responds to a specific drug, and for some patients a brand drug may be more medically-appropriate. Direct manufacturer cost-sharing support such as copay coupons can help

patients with chronic conditions access and afford needed medications, and it can help patients adhere to their drug regimens and maintain or improve their health. Therefore, we are concerned that CMS' proposal to allow these copay accumulator adjustment programs will lead to much greater out-of-pocket costs for certain patients with serious conditions, make medically-necessary medication less affordable and accessible for them, and jeopardize their health because they find it more difficult to adhere to their drug regimen. The negative effects fall disproportionately on the enrollee, because the issuer would still accept the manufacturer coupon, but the enrollee must pay much more in cost-sharing to reach their annual deductible and out-of-pocket cap.

CMS' proposal is also particularly concerning because there is no requirement for the issuer to inform the enrollee in advance that a generic is available and that their copay assistance will not count towards their annual out-of-pocket limits. Issuers in various states have implemented copay accumulator adjustment programs recently without adequately informing enrollees of the change to their policies. This has caused a lot of confusion for consumers and unexpected costs for people who rely on copay assistance to afford their medications. Also, as proposed, there is no requirement for issuers to provide an appeal process that would allow an enrollee to make the case that a brand drug is medically-appropriate for them, and therefore manufacturer assistance should be counted towards their annual out-of-pocket cap. Given these concerns, we urge CMS to not finalize this proposal.

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

Sincerely,



Holly Bode  
Vice President of Government Affairs