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April 5, 2019

Aaron Zajic
Office of Inspector General
Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

Re: OIG-0936-P; Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees

Dear Mr. Zajic:

The American Kidney Fund (AKF) appreciates the opportunity to provide comments on the Department of Health and Human Services' (HHS) proposed rule to amend the safe harbor regulation concerning discounts for prescription pharmaceuticals in Medicare Part D and Medicaid managed care.

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.

For many Americans, particularly those with chronic conditions such as kidney disease and who may have multiple comorbidities, the rising cost of prescription drugs can create a significant financial burden that can affect their medication adherence and overall health. AKF is supportive of policies that effectively balance the need to lower patient costs, protect patient access to needed medications, promote competition and innovation, and ensure patient safety.

We appreciate the administration's commitment to exploring ways to address the increasing cost of prescription drugs, and we commend HHS for the bold proposal set forth in this rule. The current system of rebates encourages manufacturers and pharmacy benefit managers (PBMs) to seek higher list prices and thus larger rebates. For manufacturers, offering a large rebate can help them negotiate a favorable placement on a formulary. For PBMs, their compensation can come from retaining a portion of the rebate, incentivizing them to seek a larger list price to net price difference. Insurers may use their portion of the rebate to lower premiums across all their enrollees. Meanwhile, many beneficiaries are disadvantaged because rebates are

not typically passed on to them at the pharmacy counter, and their cost-sharing obligations are tied to the higher list price of the medication instead of the lower net price negotiated between manufacturers and PBMs. This can be especially financially burdensome for Part D beneficiaries with chronic conditions and higher prescription drug needs and who do not qualify for the low-income subsidy, since the Part D program does not have a cap on out-of-pocket costs.

We support the objective of the proposal, which is to “lower out-of-pocket costs for consumers and reduce government drug spending in federal health care programs.” The proposed rule aims to do that by eliminating the safe harbor protection that allows for rebates between manufacturers and PBMs and replace it with a new safe harbor that would allow for discounts provided to beneficiaries at the point of sale. We agree there need to be changes in the Part D program to lower patient out-of-pocket costs, and HHS’ proposal holds a lot of promise in doing so, as demonstrated in the analyses commissioned for the proposed rule. However, as HHS points out throughout the proposal, there is also a lot of uncertainty about the rule’s effects, and “[i]t is difficult to accurately quantify the benefits of this proposed rule due to the complexity and uncertainty of stakeholder response.” Given this uncertainty, the substantial change the rule proposes, and the short timeline in which HHS seeks to implement it, we recommend that HHS delay its proposed effective date of January 1, 2020 for at least a year. This would allow additional time for analysis and consideration of stakeholder feedback, give affected entities more time to implement operational changes after a finalized rule, and give more time for beneficiary education on any finalized changes.

We also recommend that HHS exclude Medicaid managed care plans from the changes in safe harbor regulations. The Medicaid market is very different from the Part D market, and Medicaid beneficiaries are not subject to the same level of cost-sharing obligations as Part D enrollees; many have nominal or no cost-sharing for prescription drugs. Rebates in the Medicaid program also ensure beneficiary access to needed medications and allow for fewer utilization management constraints. If Medicaid managed care plans were subject to the changes in safe harbor regulations, we are concerned that may adversely affect a patient’s access to prescription drugs that are currently part of a stable drug regimen.

Finally, we recommend that if the rule is finalized, HHS should implement more comprehensive formulary reviews of Part D plans. Changing the current rebate structure in a significant way will lead to new contracting incentives between stakeholders, and formulary management may be an area in which they look for negotiation. In this new environment, we would urge HHS to ensure that formularies and benefit structures are not used to discriminate against beneficiaries with chronic conditions and certain prescription drug needs.

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

Sincerely,



LaVarne A. Burton
President and CEO