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The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 600E
Washington, DC 20201

Submitted Electronically: www.regulations.gov

OIG-0936-P

Re: 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 Secretary Azar:

On behalf of the Patient Access Network (PAN) Foundation and the patients and families we support, we appreciate the opportunity to comment on the Administration's Proposed Rule: 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.

Founded in 2004, PAN is a 501(c)(3) organization whose mission is to help underinsured people with life-threatening, chronic and rare diseases get the medications and treatment they need by providing financial assistance for their out-of-pocket costs and by advocating for improved access and affordability. PAN provides assistance through nearly 70 disease-specific programs and collaborates with national patient advocacy organizations to provide patients with the education and support they need. Since 2004, nearly 1 million underinsured patients have received financial assistance from PAN.

PAN applauds the Administration for proposing a rule to reduce drug prices and to lower out-of-pocket costs for patients—especially those needing high-cost specialty medications. The latter objective, lowering out-of-pocket costs for patients, is critically important for millions of Americans living with life-threatening, chronic and rare diseases who are disproportionately affected by high deductibles, co-payments and coinsurance.

Out-of-Pocket Costs Impede Patient Access to Life-Saving Medications

High out-of-pocket costs for prescription medications have become an insurmountable barrier to access for too many patients and have created a public health crisis for some of the sickest and most financially vulnerable among us, including people being treated for cancer, hepatitis C, multiple sclerosis, rheumatoid arthritis and many other serious illnesses. Research demonstrates that patients with serious health conditions who are exposed to high out-of-pocket drug costs are less likely to fill their prescriptions, take longer to start their treatment, and experience increased interruptions and gaps in treatment.^{1,2}

According to a recent [Kaiser Family Foundation report](#) that evaluated 30 specialty drugs used to treat the above four health conditions, Medicare Part D enrollees face thousands of dollars in out-of-pocket costs for these essential medications. For the majority of the drugs studied, average out-of-pocket costs in 2019 will exceed \$8,100, with more than \$5,400 occurring in the catastrophic phase of the Medicare Part D benefit, which has no out-of-pocket limit.

Older adults depend primarily on Medicare to cover their health expenses, but more than a quarter of Medicare beneficiaries are underinsured and spend a large share of their income on healthcare expenses, including prescription medications.³ We also know that out-of-pocket medication expenses increase with the number of chronic illnesses. For millions of older adults, living with multiple health conditions is the norm. In fact, 36 percent of Medicare beneficiaries have four or more health conditions and 15 percent have six or more.⁴

Research has also shown that patients with prescription drug co-payments equal to or greater than \$40 are much more likely to abandon their prescriptions at the pharmacy counter.^{5,6} As more than 25 million Americans over the age of 60 live at or below 250% of the federal poverty level and with out-of-pocket healthcare costs continuing to rise, too many of the nation's older adults cannot access and stay on the treatments their health care providers prescribe for them. As you know, this can have devastating effects on the health and quality of life of these patients and can result in higher costs for Medicare as untreated and undertreated patients end up using expensive emergency and inpatient care.⁷

Patients Need Out-of-Pocket Help

At PAN, we hear from patients every single day about the hardship they endure related to high out-of-pocket costs and the choices they are forced to make. Since fall of 2018, PAN has received more than 4,000 messages from patients who are grateful for the financial assistance received

from the PAN Foundation. As examples, Howard, Linda and Victor have written PAN with the following words of appreciation:

“It’s been difficult for me to talk about my cancer diagnosis. The financial help I received from PAN for my medication not only extended my life, but also took the stress out of figuring out how to pay for such high out-of-pocket costs.”

—Howard

“Before receiving a grant from PAN, I had maxed out several credit cards in order to get my medication. It often came down to missing meals or skipping doses. Getting help from PAN has enabled me to be more compliant with my medication - the assistance was truly life-saving.”

—Linda

“Had it not been for the PAN Foundation, I would have had to make a choice between getting the medication I need and putting a roof over my head. You literally saved my life.”

—Victor

Clearly, there is considerable urgency to implement policies that provide patients with relief from out-of-pocket costs for their critical medications. Anything short of this will not meaningfully address the biggest challenge facing many seriously ill Americans at the pharmacy counter.

Policy Recommendations

With regard to reducing and restraining growth in drug prices, removing the incentive that rebates provide to Pharmacy Benefit Managers (PBMs) to drive up these prices is an important first step. However, without replacing this with a specific mechanism or active measure to counter growth in drug prices, eliminating rebates alone will probably not be sufficient to achieve the objective of reducing out-of-pocket costs for Medicare beneficiaries.

In the proposed rule, the actuarial analysis provided by the Department of Health and Human Services (HHS) projects reductions in total cost sharing for beneficiaries that will exceed total projected premium increases. However, HHS also states that the impact on beneficiaries could vary greatly, with some beneficiaries seeing reductions in out-of-pocket spending, while others would experience increases. Any new regulations should require that the savings obtained from point-of-sale discounts be used to significantly reduce out-of-pocket costs for those patients generating the point-of-sale discounts. Doing so would serve two important purposes: first, it

could help promote access and adherence among patients needing specialty medications, and second, it would encourage drug manufacturers to offer meaningful discounts as a means to reduce prescription abandonment.

We recommend that the Administration consider using the first dollars from any point-of-sale discounts to offset some or all of the out-of-pocket drug costs patients must pay under the Medicare benefit. Although the amounts paid by patients are quite significant from their perspective, they often tend to be a small percentage of the total drug acquisition cost. The savings that remain after reducing the patient's costs could be shared by other stakeholders based upon how much risk each assumes and their contribution to achieving the proposed rule's two objectives. This patient-centric approach would make expensive specialty medications more affordable for Medicare beneficiaries living with serious and chronic illnesses. This approach could help align incentives among all stakeholders – patients, the Medicare program, health plans, PBMs and drug manufacturers and, in turn, achieve the objectives set out in the proposed rule.

In addition, as the Administration seeks to make prescription medications more affordable for older Americans, we urge you to consider modernizing the Medicare Part D prescription benefit by placing an annual cap on out-of-pocket costs, and by spreading these costs more evenly throughout the benefit year, through either legislative or regulatory means.

Medicare beneficiaries are the only group of insured people in the U.S. not protected by a cap on annual out-of-pocket costs. Without protection against excessive out-of-pocket prescription drug costs, Medicare beneficiaries with Part D coverage are forced, as mentioned earlier, to make difficult trade-offs or to forgo treatment altogether.⁸ As the annual Part D benefit resets each January, some beneficiaries who require expensive medications can incur many thousands of dollars out-of-pocket for their prescriptions in January alone, which requires them to have enough money early in the year to access their treatment. A recent study showed that for Medicare beneficiaries with one of the following conditions – rheumatoid arthritis, multiple sclerosis or chronic myelogenous leukemia – more than half of all out-of-pocket medication costs were incurred in the first three months of the year. For many patients, paying thousands of dollars at the beginning of the year is an enormous hardship.⁹

Conclusion

Lowering out-of-pocket drug costs for Medicare beneficiaries is an essential effort that will have a direct impact on their physical health and financial well-being. New policies that will reduce the actual price paid at the pharmacy counter are imperative if Medicare beneficiaries are to have regular access to the prescription therapies they need to manage serious, disabling, chronic and

life-threatening conditions. Ensuring affordable and unencumbered, access to prescription treatments will help facilitate disease management, improve medication adherence and maximize health outcomes, which in turn, should reduce healthcare costs.

We very much appreciate the opportunity to provide comments on the importance of lowering out-of-pocket costs for patients. If you have any questions, please do not hesitate to contact me. We thank you for your consideration of our comments and recommendations.

Respectfully submitted,



Dan Klein, MHS
President and Chief Executive Officer
Patient Access Network Foundation

¹ Doshi JA, Hu T, Li P, Pettit AR, Yu X, Blum M. Specialty Tier-Level Cost Sharing and Biologic Agent Use in the Medicare Part D Initial Coverage Period Among Beneficiaries With Rheumatoid Arthritis. *Arthritis Care Res (Hoboken)*. 2016 Nov;68(11):1624-1630.

² Doshi JA, Li P, Huo H, Pettit AR, Kumar R, Weiss BM, Huntington SF. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. *Am J Manag Care*. 2016 Mar;22(4 Suppl):s78-86.

³ Schoen C, Solis-Roman C. On Medicare But At Risk: A State-Level Analysis of Beneficiaries Who Are Underinsured or Facing High Total Cost Burdens. Available at: <https://www.commonwealthfund.org/publications/issue-briefs/2016/may/medicare-risk-state-level-analysis-beneficiaries-who-are>.

⁴ Centers for Medicare and Medicaid Services. Multiple Chronic Conditions. Available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main.html.

⁵ IQVIA. Patient Affordability Part Two. Implications for Patient Behavior and Therapy Consumption. Available at:

⁶ [Shrank WH](#), [Choudhry NK](#), [Fischer MA](#), [Avorn J](#), [Powell M](#), [Schneeweiss S](#), [Lieberman JN](#), [Dollear T](#), [Brennan TA](#), [Brookhart MA](#). The epidemiology of prescriptions abandoned at the pharmacy. *Ann Intern Med*. 2010;153(10):633-40.

⁷ National Council on Aging. Economic Security for Older Adults. Available at: <https://www.ncoa.org/news/resources-for-reporters/get-the-facts/economic-security-facts/>.

⁸ Doshi JA, Pettit AR, Li P. Addressing Out-Of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored. Available at: <https://www.healthaffairs.org/doi/10.1377/hblog20180724.734269/full/>.

9 Doshi JA, Li P, Pettit AR, Dougherty JS, Flint A, Ladage VP. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon". *Am J Manag Care.* 2017;23(3 Suppl): S39-S45.