April 7, 2019

Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SE
Washington, DC 20201

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; OIG-0936-P

Dear Secretary Azar,

On behalf of the Cancer Support Community (CSC), we appreciate the opportunity to submit the following comments. We are supportive of efforts to eliminate perverse incentives in the health care system but urge routine monitoring and adjustment to ensure that patient out-of-pocket spending and access to appropriate therapeutics are not negatively impacted. However, we specifically ask that the U.S. Department of Health and Human Services (HHS) routinely monitor and evaluate the effects of such a sweeping policy and adjust if the ultimate impact on patients results in higher out-of-pocket spending or impedes access to appropriate treatments.

As the largest professionally led nonprofit network of cancer support worldwide, the Cancer Support Community (CSC), including its Gilda’s Club affiliates, is dedicated to ensuring that all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community. CSC achieves its mission through three areas: direct service delivery, research, and advocacy. The organization includes an international network of Affiliates that offer the highest quality social and emotional support for people impacted by cancer, as well as a community of support available online and over the phone. The Research and Training Institute conducts cutting-edge psychosocial, behavioral, and survivorship research. CSC furthers its focus on patient advocacy through its Cancer Policy Institute, informing public policy in Washington, D.C. and across the nation. Overall, we deliver more than $50 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

The U.S. Department of Health and Human Services (HHS) is proposing to amend the safe harbor regulation concerning discounts, which are defined as certain conduct that is protected from liability under the Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act). The amendment would revise the discount safe harbor to explicitly exclude from
the definition of a discount eligible for safe harbor protection certain reductions in price or other remuneration from a manufacturer of prescription pharmaceutical products to plan sponsors under Medicare Part D, Medicaid managed care organizations as defined under section 1903(m) of the Act (Medicaid MCOs), or pharmacy benefit managers (PBMs) under contract with them. In addition, the Department is proposing two new safe harbors. The first would protect certain point-of-sale reductions in price on prescription pharmaceutical products, and the second would protect certain PBM service fees.

The proposal notes that the Secretary is concerned that rebate arrangements are neither beneficial to health care programs and beneficiaries, nor are they innocuous. Ultimately, HHS believes that the changes set forth in the proposal will improve alignment of incentives among those parties that may curb list price increases, reduce financial burdens on beneficiaries, lower or increase Federal expenditures, improve transparency, and reduce the likelihood that rebates would serve to inappropriately induce business payable by Medicare Part D and Medicaid MCOs.

Ultimately, CSC supports changes to the health care system that eliminate perverse incentives and drive beneficiary cost sharing and out-of-pocket spending down. However, it is critical that the effects of such a sweeping policy be routinely monitored and adjusted if the ultimate impact on patients results in higher out-of-pocket spending or impedes access to appropriate treatments.

**Beneficiary Cost Sharing**

As noted by in this proposal, Milliman (2019) estimates Part D premium increases from $3.20 to $5.64 per beneficiary per month. Further, HHS assumes that a beneficiary taking a brand name drug in a competitive class may see his or her coinsurance-based cost sharing for the drug reduced significantly, if behavioral changes in response to this policy result in rebates largely being converted to point of sale discounts. Additionally, HHS notes that although the majority of beneficiaries would see an increase in their total out-of-pocket payments and premium costs, reductions in total cost sharing will exceed total premium increases.

The Milliman study (2019) goes further to state that not all beneficiaries will see equal benefit. For individuals with prescriptions that do not receive rebates, they will see an increase in premiums without a concordant cost savings at the pharmacy counter. Plan sponsors with very high manufacturer rebate levels may experience the highest increases in premiums while plan sponsors with lower than average rebate levels may experience a decrease in premiums.

**Evaluation**

HHS notes a degree of uncertainty regarding the impact of this rule due to the range of strategic behavior changes stakeholders may make in response to this rule. It is critical that HHS evaluate the impact of this proposal on beneficiaries. Milliman (2019) states that it is unlikely for there to be no behavioral changes. If stakeholders make changes that are ultimately not in the best interest of patients and will negatively impact beneficiary out-of-pocket spending, how will HHS address this? Milliman (2019) also predicts increased formulary controls, higher price concessions, and lower price trends which would lead to great average member savings. If patient access to appropriate therapeutics is impacted by behavior changes as a result of this rule, how will HHS address this?
HHS must evaluate the impact of each of the Administration’s changes on patients. This includes each individual policy as well as the confluent impact the various policies (such as the International Pricing Index and changes to the Part D six protected classes) will have together. As evidenced by the Administration’s Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, there are a host of potential changes at play and it is unclear what the summation of changes will mean to patients. It is incumbent upon the Administration to track the impact of these changes with a primary goal of understanding how patients are faring and if out-of-pocket spending has been reduced or access to appropriate therapeutics has been impeded in any way.

Finally, if this proposal does proceed, it is incumbent upon HHS to provide information to beneficiaries in clear, understandable terms. If premiums do increase, this is one of the most visible and understandable aspects of patient out-of-pocket spending, and it is important that patients understand the potential impact.

In conclusion, CSC appreciates the opportunity to comment on this proposal and the intention of the Administration to lower patient out-of-pocket costs. We are supportive of efforts to eliminate perverse incentives in the health care system but urge routine monitoring and adjustment to ensure that patient out-of-pocket spending and access to appropriate therapeutics are not negatively impacted. If we can serve as a resource to the Administration, please contact us at efranklin@cancersupportcommunity.org or 202.650.5369.

Sincerely,

Elizabeth F. Franklin, LGSW, ACSW
Executive Director, Cancer Policy Institute
Cancer Support Community

References


Retrieved from
