

April 8, 2019

Daniel R. Levinson  
Inspector General  
US Department of Health and Human Services  
330 Independence Ave, SW  
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; Proposed Rule [RIN 0936-AA08]

Dear Mr. Levinson,

On behalf of the Endocrine Society, I offer these comments on the Proposed Rule related to removal of safe harbor protections involving prescription medications. The Endocrine Society is the world's oldest and largest professional organization of endocrinologists, representing the interests of over 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders like diabetes, obesity, osteoporosis, thyroid disease, and infertility. Drug pricing reform is critical to us and the patients our members treat. Our member endocrinologists have difficult conversations every day with their patients who cannot afford the drugs needed to keep them alive or avoid complications of their disease.

Insulin is an important example of why drug pricing reform is needed. The cost of insulin has nearly tripled in the past fifteen years, making it difficult for many people to afford this medication and effectively manage their diabetes. This has put patient safety in jeopardy as patient self-rationing of their insulin may lead to unnecessary complications or death and should not be a cost-savings approach that people with diabetes are forced to choose. The Endocrine Society supports policy changes that provide physicians and patients with transparent information on the out-of-pocket cost of medications and lower-cost alternatives or reduces the amount that a patient must pay out-of-pocket.

The Proposed Rule would revise the discount safe harbor to explicitly exclude price reductions or other remuneration from product manufacturers to plan sponsors (Medicare Part D, Medicaid Managed Care, and Pharmacy Benefit Managers (PBMs)). It also includes two new safe harbors: (1) protecting certain point-of-sale reduction in price on prescription drugs; and (2) protecting certain PBM service fees.

In general, we support efforts to eliminate rebates that artificially inflate drug prices or policy changes that pass the rebates on to patients at point-of-sale. The current rebate system creates perverse incentives that result in manufacturers offering increasingly higher rebates in order to guarantee placement on the preferred drug tier to increase sales of their medications. While many patients see little change in their out-of-pocket expenses as these drug prices rise, those who are un- or under-



insured or who are on high-deductible health plans must pay the full list price of the medication.

While we support the proposal to eliminate rebates, we have concerns about how this change to the pricing system will impact patients and the system overall. We believe some consumer protections need to be in place to ensure assumptions about market behavior are realized. We believe the following questions must be addressed before the proposed rule is finalized:

- Without rebates or other forms of discounting, is it safe to assume that manufacturers will compete on the list price on similar medications?
- How will this policy ensure that prices of prescription drugs are reduced?
- The Proposed Rule included several estimates on the impact on premiums and out-of-pockets costs, with significant variations. Many questions remain about how premiums will be impacted. Will they increase more or less than potential out-of-pocket cost savings from drug rebates?
- Who will have oversight of PBMs and manufacturers to ensure that rebates or other discounts are not occurring?
- Will administrative fees to PBMs increase and how will that impact consumers?
- What is the incentive for PBMs to reduce costs if they receive a flat fee?
- Will local pharmacies continue to exist, or will patients be required to use PBM-based mail-order facilities?
- How will this change in Medicare Part D and Medicaid Managed Care impact the pricing system in the commercial market?
- Will it be possible for the Rule be finalized and implemented before the proposed January 1, 2020 effective date?

Thank you again for considering our comments on the Proposed Rule. Pursuing opportunities that can make insulin affordable to all patients is a top priority of the Society and our members. If we can be of additional assistance, please contact Mila Becker, JD, Chief Policy Officer at [mbecker@endocrine.org](mailto:mbecker@endocrine.org).

Sincerely,

E. Dale Abel, MB.BS., D.Phil. (M.D., Ph.D.)  
President, Endocrine Society