April 8, 2019

Daniel R. Levinson
Department of Health and Human Services
Office of Inspector General
Attention: OIG-0936-P
Cohen Building, Room 5527
330 Independence Avenue, SW
Washington, DC 20201

RE: RIN 0936-AA08 (*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 Inspector General Levinson:

Established in 1943, the American Academy of Allergy, Asthma, & Immunology is a professional organization with more than 7,000 members in the United States, Canada, and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. We write in reference to the above-referenced proposed regulation. We hope our feedback is useful as you finalize the various policies outlined in the proposal.

The AAAAI is joined in this letter by three organizations dedicated to supporting patients with allergic/immunologic disease: the Allergy and Asthma Foundation of America, the American Partnership for Eosinophilic Disorders, and The Mastocytosis Society. Together these organizations represent hundreds of thousands of patients across the United States, including many facing the extraordinary issues of the rare disease community.

Broadly speaking, the regulation proposes the following:

- Elimination of safe harbor protection from antikickback law for certain price reductions on prescription pharmaceuticals from manufacturers to plan sponsors under Medicare Part D and Medicaid Managed Care Organizations.
- Addition of two new safe harbors. The first would protect discounts between those same entities if such discounts are given at the point of sale to beneficiaries, and meet certain other criteria. The second would protect certain fees pharmaceutical manufacturers pay to PBMs for services rendered to the manufacturers.

Throughout the proposed rule, the agency makes a compelling argument that the current rebate system is disadvantaging Medicare beneficiaries and is negatively affecting the program's

finances. With regard to beneficiaries, rebates and discounts are not passed through, so that beneficiaries do not see the benefit of any reduction in their out-of-pocket cost-sharing as a result of these manufacturer-PBM negotiations. Additionally, because a product with a higher list price has the potential to generate a higher rebate for the PBM, the PBM may prefer higher-priced products over cheaper alternatives. As a result, a manufacturer that lowers its list price may find itself "punished" with less preferred formulary placement.

Driving utilization of more expensive products when cheaper alternatives are available has a negative impact on Medicare's finances as well. Additionally, estimated rebate payments are supposed to be reflected in premium projections at the beginning of the plan year but, as the rule notes, there is evidence showing that plans are consistently underestimating their expected rebate revenue, resulting in premiums that are higher than they should be. Given that Medicare pays for a large portion of premiums, this disadvantages the program's financial health.

Opponents of the proposal have argued that eliminating rebates will result in an increase in premiums, given that, in today's system, these payments are used to lower premiums (though, as explained above, not to the full extent). The Administration acknowledges that it is impossible to accurately predict the exact financial impact of the proposed change. However, the most likely scenario is that all beneficiaries will experience a small increase in premiums. This increase will be more than offset by out-of-pocket savings for beneficiaries with high drug costs.

The proposed regulation begins to undo some of the perverse incentives in the current drug pricing system. Allowing manufacturers to provide discounts directly to patients instead of providing rebates to middlemen is an intuitive change that will benefit Medicare beneficiaries. We support finalization of this proposal.

We would be remiss if we did not note that the rule lacks any requirement for manufacturers to provide discounts to patients. We acknowledge that such a requirement is outside the jurisdiction of the Office of the Inspector General, but we hope that HHS will track whether drug prices for patients are reduced as a result of this proposal and, if not, will consider a discounting requirement.

On behalf of our members and the patients we serve, thank you for considering our feedback. Please contact Sheila Heitzig, AAAAI Director of Practice and Policy, at (414) 272-6071 or sheitzig@aaaai.org if you require any follow-up information or have any questions.

Sincerely,

American Academy of Allergy, Asthma, & Immunology
Allergy and Asthma Foundation of America
American Partnership for Eosinophilic Disorders
The Mastocytosis Society