Alliance of Specialty Medicine

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March 18, 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: "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" (RIN 0936-AA08; OIG-0936-P)

Inspector General Levinson:

The Alliance of Specialty Medicine (the "Alliance") represents more than 100,000 specialty physicians from fifteen specialty and subspecialty societies. The Alliance is deeply committed to improving access to specialty medical care through the advancement of sound health policy.

We write in reference to the proposed regulation entitled "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" ("the proposed rule"). As an organization representing specialty and subspecialty physicians, we wish to thank the Administration for its continued focus on reducing out-of-pocket costs for our patients. We hope our viewpoints will be useful as you consider finalizing policies outlined in the proposed rule.

We have noted in past communications that we have become concerned about the practices of pharmacy benefit managers (PBMs) and their role in the pharmaceutical supply chain. We are not alone in these concerns. For example, MedPAC has raised concerns about "mixed incentives," particularly in the context of PBM-owned specialty pharmacies.[1] As the proposed rule notes in

[1] http://www.medpac.gov/docs/default-source/default-document-library/pbms-and-specialty-pharmacies---final.pdf?sfvrsn=0.

detail, the current rebating system creates perverse incentives that are not serving patients well. Most notably from the perspective of the patients we treat, beneficiaries are not currently benefiting from price concessions in the form of reduced cost-sharing, as their coinsurances are based on list prices. Additionally, our member physicians report ever-increasing and aggressive utilization management tactics by PBMs that are interfering with the practice of medicine.

Further, as the proposed rule highlights, the current rebate-driven system may create an incentive for PBMs to drive utilization of the more expensive product through preferred formulary placement in cases where less expensive options are available. The lower priced product would generate a smaller rebate since the spread between the list and net prices would be narrower. The cheaper product also has less potential to generate price protection payments for the PBM. Thus, that product may be moved to a less preferred formulary placement or even removed from formulary altogether.

For these reasons, as the proposed rule states, the rebate system has been "cited as a potential barrier to lowering drug costs" and "works to the disadvantage of beneficiaries, and the Federal health care programs." This system, which financially disadvantages the patients it is intended to serve, is ripe for reform.

To better realign incentives, the proposed rule leverages antikickback law. First, the rule proposes to eliminate 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. In addition, the proposed rule would add two new, narrow 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.

While the Administration acknowledges that it is difficult to predict the behavioral response by manufacturers, its hope is that manufacturers will move away from retroactive rebates, to upfront discounts instead. It is important to note that the rule does not require this. Rather, the rule identifies a revenue stream that has created perverse incentives and is thus problematic for federal health programs and their beneficiaries, and seeks to eliminate that revenue stream. This is a key first step in improving our pharmaceutical supply chain.

The Administration acknowledges that the financial impacts of the proposed rule are difficult to predict. The proposed rule provides six different modeled scenarios, each with widely varying impacts for government payments as well as beneficiary costs. Assuming no behavioral response

by any stakeholder, the modeled scenarios estimate that enrolled beneficiaries may see premiums increase 14 to 19%, but average cost-sharing will decrease by 11 to 14%. As for government payments, "subsidies for low income enrollees' premiums and cost sharing will likely increase and be partially offset by reduced payments to plans for reinsurance, increasing overall by 2 to 14%[.]" Again, none of these estimates assume any behavioral responses by any stakeholders in the supply chain, including beneficiaries.

These widely varying estimates provide both proponents and opponents of the proposed rule the ability to cherry-pick individual data points to fit their narratives. However, if finalized as proposed, these policies will result in all beneficiaries experiencing a nominal premium increase and some beneficiaries experiencing significant out-of-pocket savings – mostly beneficiaries using a lot of prescription drugs or using high-cost prescription drugs.

To undo the reverse incentives in our pharmaceutical supply chain, the Alliance supports the Administration's proposal to eliminate the antikickback safe harbor for certain payments from pharmaceutical manufacturers to insurers and pharmacy benefit managers. Furthermore, we support incentives to reduce out-of-pocket drug costs for patients and, as such, we support providing a new antikickback safe harbor for price concessions that go directly to the patient at the point-of-sale.

Thank you for allowing us to comment on behalf of practicing specialists and the patients we serve. Should you have questions or require any additional information, please do not hesitate to reach out to any of the undersigned organizations.

Sincerely,

American Association of Neurological Surgeons
American Gastroenterological Association
American Society of Cataract and Refractive Surgery
American Society for Dermatologic Surgery Association
American Society of Plastic Surgeons
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons