April 8, 2019

The Honorable Alex Azar  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201  

The Honorable Daniel R. Levinson  
Inspector General  
Office of Inspector General  
Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201  


Dear Secretary Azar and Inspector General Levinson,

The American Academy of Dermatology Association (AADA), which represents more than 13,800 dermatologists nationwide, would like to provide the following comments in response to the proposed rule to amend the safe harbor regulation concerning discounts by the Department of Health and Human Services (HHS) Office of Inspector General (OIG). Dermatologists diagnose and treat more than 3,000 diseases, including skin cancer, psoriasis, immunologic diseases and many genetic disorders. One in four Americans suffers from a skin disease. As dermatologists on the front lines fighting skin cancer and treating numerous skin diseases, the AADA has made patient access to affordable treatments and transparency in drug pricing a top priority. While the AADA understands the need to manage the unpredictable and growing costs of health care, including therapy, it believes that should not be achieved at the risk of harming or by placing the economic burden on patients.

In March 2015, the AADA created an Ad Hoc Task Force on Drug Pricing and Transparency, which is charged with investigating the dramatic increases in generic and specialty medications costs and using this information to advocate for both price transparency and for patients’ access to affordable and effective generic, branded and specialty medications. To that end, the Task Force has led the AADA to research and educate our membership and their patients about the issues, develop policy positions, and advocate for meaningful reform.

Despite ongoing work, patients continue to experience price increases for both generic and brand drugs prescribed by their dermatologists. A Journal of the American Academy of Dermatology (JAAD) study of 51 generic topical dermatologic medications found that between 2005 and 2016, mean prices increased by 273% while inflation only increased by 23%. The greatest price change was an increase of 2,529% for
nystatin-triamcinolone acetonide cream to treat fungal skin infections.\(^1\) Additionally, the OIG recently found that “total reimbursement for all brand name drugs in Part D increased 77% from 2011 to 2015, despite a 17% decrease in the number of prescriptions for these drugs.” Among the top twenty drugs with the highest percentage increases in unit cost during that time period are several dermatological drugs that experienced over 1,000% increase in price.\(^2\) When drugs become cost-prohibitive for patients, they often go without or do not take their medication as prescribed (e.g., taking less frequently). Access to affordable medication for these conditions is not only medically necessary, it is life-changing, and often life-saving.

The AADA appreciates the opportunity to provide comments to HHS and OIG and hope the agencies will take the AADA’s recommendations into consideration when developing future policies.

**Increasing Transparency of the Drug Supply Chain**

The AADA applauds the Administration’s efforts to increase transparency of the drug pricing supply chain. The processes utilized in setting drug prices, both brand and generic, should be readily available and easy for patients to access. Patients and physicians should have access to real-time cost information available at the point of prescribing to ensure cost considerations are a meaningful part of the physician-patient decision-making process.

The AADA appreciates the Administration’s recognition of the role that pharmacy benefit managers (PBMs) play in contributing to the rise in drug prices. Originally created to manage prescription drug plans on behalf of beneficiaries, PBMs have grown into significant stakeholders in the drug supply chain. At present, three PBMs control nearly three-quarters of the PBM market.\(^3\) The AADA supports pharmaceutical manufacturers disclosing the discounts and rebates provided to PBMs, and PBMs disclosing how much of the rebates and discounts are passed on to the patient. The AADA recognizes the need for a comprehensive solution across the drug supply chain to preserve access to treatments and to address rising drug costs. The enigmatic operation of PBMs is just one of several factors creating barriers for patients to access their medications. Therefore, while, the AADA supports transparency in the structure in which PBMs operate and the negotiation process of PBMs, what will be the final rule must not negatively impact patients. Below the AADA highlights some of the potential areas of concern.

**Increased Patient Cost-Sharing**

CMS proposes to eliminate the safe harbor protection for rebates paid by manufacturers to PBMs in Part D and Medicaid managed care organization (MCO) plans. Two new safe harbors are proposed by CMS; one allows manufacturers to apply a reduction in the price of prescription pharmaceutical products at the point-of-sale and one allows for specific fixed fees that pharmaceutical manufacturers pay to PBMs. These changes do not apply to rebates given to wholesalers, hospitals, physicians, pharmacies and third party payors in other Federal health care programs.

The AADA is concerned that some of the downstream effects of the proposed rule could increase the financial responsibility of Medicare and Medicaid beneficiaries. The economic analyses presented in the proposed rule show that patients on high cost drugs will likely experience lower out-of-pocket costs. The reasoning is that if the list prices of drugs go down then the cost sharing for patients will be based on a

---


\(^3\) Health Strategies Group, Research Agenda 2017: PBM Trends & Strategic Implications, February 2017
lower dollar amount. Despite this prediction, there are still patients who utilize high cost drugs with limited or no competition. These specific drugs will have no incentive to lower list prices.\textsuperscript{4} Therefore, many patients on high cost drugs will see no financial relief. It is also predicted that the proposal may cause premiums to rise for all Part D beneficiaries.

Even with these concerns, we recognize that transparency in pricing will increase patients’ awareness of the cost to benefit ratio of the prescribed medication and empower the consumer to shop for the best price for the medications deemed most helpful for their condition.

**List Prices**

It is unknown if the prices of drugs will decrease under this proposal. There is no mechanism in place to adjust the prices. The proposed rule relies on manufacturers reducing list prices with the money that would have gone to rebates. In a previous report to Congress, the Congressional Budget Office predicts that in a scenario where the rebates are public, it “would facilitate tacit collusion among those manufacturers, which would tend to raise drug prices.”\textsuperscript{5} The AADA recommends the Administration continue examining all potential positive and negative impacts this proposal could have on patients before finalization and implementation.

**Price Spikes**

Today, dermatologists do not know and cannot find the accurate price of the drug at the point of dispensing. The prices of drugs can vary greatly from day-to-day and even within the same zipcode. Even if physicians were to know the price, it often changes by the time the patient picks up the prescription at the pharmacy.

In response to these challenges the AADA requests information on how the proposed system will adjust to sudden price spikes? Specially, how will the patient’s cost-sharing responsibilities be impacted?

**Further Clarity on Negotiating Provisions**

The proposal relies on upfront discounts to replace rebates. The AADA seeks clarification on how PBMs will negotiate for discounts without the use of rebates. What compensation can PBMs receive and how will they be incentivized to negotiate lower drug prices for patients? How will drug manufacturers negotiate for placement on the formulary of health plans?

Further clarity is also needed on how this proposal will affect existing safe harbors. Are there loopholes in other safe harbors, such as the Group Purchasing Safe Harbor for PBMs, that may permit the rebate-based system to continue?

If the above mentioned provisions are included and further defined, then this would likely allow for more competition and lower drug costs, such as biosimilars, to gain entry into the market. At the end of the day, the AADA supports reduced cost-sharing for patients, but further clarity on these issues is necessary for this to be achieved through this rulemaking.

**Conclusion**

\textsuperscript{4} Dusetzina SB, Bach PB. Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle. JAMA. Published online March 06, 2019. doi:10.1001/jama.2019.2445

The AADA welcomes the opportunity to engage with you and to continue our partnership with HHS and OIG in these efforts to reduce drug costs for patients. Please contact Ashley John, Manager, Advocacy and Policy at (202) 609-4355 or ajohn@aad.org if you have any questions or if we can provide additional information.

Sincerely,

George J. Hruza, MD MBA FAAD
President, American Academy of Dermatology

Cc:
Barbara Greenan, Senior Director, Advocacy and Policy
Leslie Stein Lloyd, JD, CAE, Director, Regulatory and Payment Policy