March 10, 2023

Meena Seshamani, M.D. Ph.D.
CMS Deputy Administrator
Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
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Submitted via email: IRARebateandNegotiation@cms.hhs.gov

Re: CMS-1800-NC - Medicare Part B and Part D Prescription Drug Inflation Rebate Program

Dear Dr. Seshamani,

On behalf of the American Academy of Dermatology Association (AADA), thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) initial guidance for the Medicare Part B and Medicare Part D Prescription Drug Inflation Rebate Program.

As the leading society in dermatological care, the AADA represents nearly 16,500 dermatologists nationwide. The AADA is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology, and driving continuous improvement in patient care and outcomes while reducing the burden of skin disease.

The AADA understands the need to manage growth in health care spending and applauds CMS' efforts to curb rising drug prices, a driver of health care spending. Dermatologists are committed to delivering high-value, cost-effective care to patients. Rising drug prices have made it increasingly difficult for dermatologists to prescribe cost-effective medications and for their patients to access affordable treatment.

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While managing drug prices ideally should improve access to affordable medication, the AADA is concerned that access to treatment may be hindered without multiple safeguards in place to identify and respond to unintended consequences surrounding implementation of the Medicare Part B and Medicare Part D Prescription Drug Inflation Rebate Program.

Increased Transparency into Drug Pricing

The AADA supports transparency in drug pricing and encourages CMS to consider various factors behind drug price increases that exceed the rate of inflation. For example, a pharmaceutical manufacturer may experience unexpected market or manufacturing conditions that impact a drug with a low margin. Depending on the price increase needed to sustain a positive margin, the manufacturer may choose to exit the market if the drug is not financially sustainable after rebates. For this reason, CMS should review historical pricing and consider current factors that may justify price increases that would otherwise result in owing rebates. This may prevent manufacturers of drugs that are fairly priced from exiting the market, which could thereby help to maintain access to said drugs.

Reporting and Review Process for Drug Shortages or Severe Supply Chain Disruptions

Drug shortages can significantly reduce access to recommended care and lead to negative patient outcomes. For several years, dermatologists have faced reduced access to essential drugs for dermatological procedures due to the national shortage of vital medications. For example, several dermatologists have limited to no supplies of lidocaine and lidocaine with epinephrine, two local anesthetics essential for dermatologic procedures. This ongoing drug shortage has resulted in the delay of medically necessary procedures for patients with critical needs, particularly for skin cancer patients undergoing Mohs surgery to remove cancerous cells from their skin using a local anesthetic in the office setting. Without the requisite dosage of lidocaine or lidocaine with epinephrine, there could be increased bleeding at the surgical site, potential post-operative complications, or an inability to perform these curative office procedures at all.

Although AADA recognizes the need to support manufacturers during times of shortages, we are concerned about potential opportunities to benefit from drug shortages. Pharmaceutical manufacturers often have asymmetric information about the conditions causing shortages and may even have control over some of these conditions. For instance, manufacturers have intimate knowledge of market conditions and could increase production of a drug in shortage just up to a level that would keep the drug on the shortage list and thereby ensure it qualifies for rebate reductions or waivers.

The AADA urges CMS to implement a reporting and review process on drug shortages and reductions or waivers during times of shortage. The AADA supports a process that would

require manufacturers to provide information on the circumstances surrounding the shortage and justification for reductions. Further, the AADA encourages CMS to establish a process to verify the information provided by the manufacturer. This process could help to support manufacturers in circumstances beyond which they have control while minimizing opportunities to benefit from shortages to avoid paying rebates.

Ongoing Review to Ensure Program Integrity

The AADA encourages CMS to implement an ongoing process to review the broad impact of the program on various stakeholders, including but not limited to, Medicare and other payers, pharmaceutical manufacturers, physicians, and patients. Through this review, CMS can help to ensure that the Medicare Part B and Medicare Part D Prescription Drug Inflation Rebate Program has maintained access to necessary treatment while also managing drug prices.

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Thank you for the opportunity to provide comments on CMS' Medicare Part B and Medicare Part D Prescription Drug Inflation Rebate Program guidance. If you have any questions about the recommendations in this letter, please contact AADA Practice Advocacy Manager Teresa Salaway at tsalaway@aad.org or (847) 240-1695.

Sincerely,

Mark D. Kaufmann, MD, FAAD
President
American Academy of Dermatology Association