April 11, 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-NC2 - Medicare Drug Price Negotiation Program Guidance

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 Drug Price Negotiation Program.

The AADA is the leading society in dermatological care, representing more than 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 applauds CMS' efforts to lower prescription drug prices and, ultimately, costs for Medicare beneficiaries while strengthening the Medicare program. Dermatologists are committed to prescribing the most effective and affordable treatment for patients, but increasingly high costs of medications have placed an economic burden on patients and impeded their access to treatment.

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The AADA affirms that Americans should have access to affordable, quality dermatological health care, including medications and treatment.[1] Access to affordable medication is not only medically necessary but can also be life-changing and life-saving for patients with conditions that have a substantial impact on their physical and mental health.

As the Medicare Drug Price Negotiation Program intends to increase access through lower drug prices, the AADA offers the following comments in support of improved patient access to affordable, innovative medication and treatment.

Requirements for Manufacturers of Selected Drugs

Price setting for prescription drugs, as well as the cost that patients pay for drugs, has long been an opaque process in the United States. The lack of transparency in the process has historically lent itself to significant power for those setting prices in the industry. CMS has an opportunity to increase transparency and establish accountability for drug pricing through its published explanation for maximum fair prices (MFPs).

The AADA encourages CMS to increase transparency into the price-setting process and provide clear justification for drug pricing.[2] When determining the information to include in the explanation for the MFP, there must be careful evaluation as to whether requests to withhold certain information are in the interest of protecting sensitive business information or undermining the establishment of a more transparent price-setting process.

Negotiation Factors

High launch prices and major price increases continue to raise questions about the relationship between drug pricing and clinical evidence and efficacy. Recent studies have found that drug price hikes are often not supported by new clinical evidence of improvement in health benefit.[3–5] By considering evidence about the effectiveness of a drug and its therapeutic alternatives, CMS is making forward progress in relating a selected drug's price to its clinical benefit.

The AADA supports CMS' plan to base drug pricing on high-quality data, consider input from the public, and consult subject matter and clinical experts. As part of this process, **the AADA encourages CMS to consult with relevant specialties and their respective specialty societies for their experience and expertise with the selected drug and its therapeutic alternatives.**[6]

Specialty societies and the physicians that they represent have direct, real-world experience with the equivalence and effectiveness of available treatment options on different Medicare populations. With a breadth of expertise, specialty societies are also well-positioned to provide suggestions for how to directly compare therapeutic alternatives with the selected drug,

including situations when multiple therapeutic alternatives exist or when the selected drug and its alternatives have different dosage forms, vehicles, strengths, and frequency of use.

Negotiation Process

Drug development is a lengthy, rigorous process that requires a significant financial investment. According to the pharmaceutical industry, it takes over ten years[7] and nearly a billion dollars[8] to over two billion dollars,[9] on average, to bring a new drug to market. Less than 12% of drugs that enter clinical testing will later receive approval.[9]

Innovation should continue to be promoted so that patients have access to the life-changing and life-saving medications that result from drug research and development. While understanding the need to manage healthcare costs, the AADA believes that this goal should not be achieved at the cost of patient outcomes.[2] If innovation in drug development appears disincentivized, there could be a future downstream impact on patient outcomes.

For that reason, the AADA supports CMS' plan for adjusting the price during the negotiation process based on both clinical benefit and manufacturer-specific data elements. When adjusting the starting price based on clinical benefit, the AADA again encourages CMS to actively consult with specialty societies for their real-world experience and clinical expertise.[6] Additionally, CMS can help to promote innovation by taking into account factors related to the history of drug development and current state of production and distribution.

Compliance and Oversight

Some physician practices acquire medications through a "buy-and-bill" model, in which a practice purchases (buys) a drug and later submits a claim for payment (bills) after administering the drug to a patient. CMS addresses concerns of practices that utilize a "buy-and-bill" model by requiring that the Primary Manufacturer either a) ensure the dispensing entity's acquisition cost is no greater than the MFP or b) retrospectively reimburse the difference between the original acquisition cost and the MFP. In either case, practices will not be reimbursed less than the acquisition cost of the drug.

The AADA appreciates CMS addressing this concern and further establishing a process for reporting instances in which the MFP was not made available to dispensing entities, MFP-eligible individuals, and other providers or suppliers. **The AADA encourages CMS to consider creating an online form for reporting MFP violations in addition to establishing a toll-free phone number.** Similar to the No Surprises Consumer Complaint Form (https://nsa-idr.cms.gov/consumercomplaints/s/?language=en_US), an online form could help to guide users through the process, ensure all needed information is collected, create a mechanism for tracking

issues, and streamline the entire process. This technology solution may help to ameliorate burdens related to reporting and monitoring violations.

To expand on the plan for monitoring and compliance, the AADA encourages CMS to implement a broader process to monitor the impact of the Negotiation Program on various stakeholders over time. Stakeholders could include the Medicare program, other non-Medicare payers, Medicare beneficiaries, the pharmaceutical industry, and physicians and non-physician clinicians.

Through a broader monitoring process, CMS should review the impact of the program on drug spending and identify any unintended consequences, such as related to drug prices, access to drugs, and new drug development. By monitoring the broad impact of the Negotiation Program, CMS can help to ensure that the Medicare Drug Price Negotiation Program has achieved its goal of reducing drug prices while preserving and improving access to innovative, affordable medication and treatment.

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Improving patients' access to affordable medication and treatment is a priority for the AADA. The AADA appreciates the opportunity to provide comments on CMS' initial guidance for the Medicare Drug Price Negotiation Program. 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) 240-1965.

Sincerely,

Terrence A. Cronin Jr., MD, FAAD
President
American Academy of Dermatology Association

References

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