Congress of the United States
Washington, DC 20515

February 5, 2025

The Honorable Eugene L. Dodaro
Comptroller General
United States Government Accountability Office
441 G Street NW
Washington, D.C. 20548

Dear Mr. Dodaro:

The high costs of prescription drugs in the United States have, for too long, created financial hardships and affordability challenges for people across the country, as well as our health care system and the federal government. The Government Accountability Office (GAO) has actively engaged in work to identify the factors that affect prescription drug pricing in the United States and repeatedly highlighted that the U.S. spends more than other countries for brand name prescription drugs.[1] In fact, in 2020, GAO found that the prices of 20 brand-name drugs in the U.S. were 2 to 4 times higher than prices in comparison countries.[2] Similarly, in 2022, a RAND analysis found that U.S. prices for prescription drugs were nearly 2.78 times as high as prices in comparable countries.[3]

Given the financial impact of high prescription drug prices in the United States, Congress enacted historic provisions in the Inflation Reduction Act (IRA) to lower the price of prescription drugs, including through the creation of the Medicare Drug Price Negotiation Program.[4] The law provided the Secretary of the Department of Health and Human Services (HHS) with the authority to directly negotiate with drug manufacturers the price of certain drugs under Medicare, and since the enactment of the IRA, HHS and the Centers for Medicare & Medicaid Services (CMS) have worked to implement these critical reforms.

The law required the Secretary to select a certain number of qualifying single source drugs each year and negotiate with the manufacturers of such drugs a maximum fair price, while taking into consideration certain factors, such as research and development costs, current unit costs, market data and revenue and sales volume data, and evidence about alternative treatments, such as the extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of those alternatives.[5]

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[1] Government Accountability Office, *Prescription Drug Spending* (https://www.gao.gov/prescription-drug-spending) (accessed Feb. 4, 2025).

[2] Government Accountability Office, *Prescription Drugs: U.S. Prices for Selected Brand Drugs Were Higher on Average than Prices in Australia, Canada, and France* (Mar. 29, 2021) (GAO-21-282).

[3] RAND, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data* (Feb. 1, 2024).

[4] Pub. L. No. 117-169 (2022).

[5] *Id.* at Sec. 1194(e).

As a result, on August 15, 2024, CMS announced the maximum fair prices of 10 selected drugs under Medicare Part D that will go into effect beginning on January 1, 2026, based on negotiations conducted with participating drug manufacturers using the parameters delineated in the law. When these prices go into effect in 2026, people enrolled in Medicare Part D are estimated to save $1.5 billion in one year alone due to these negotiations.[6]

The IRA also directed the Comptroller General to provide oversight of the "distribution and use of funds" appropriated under the law, as well as "whether the economic, social, and environmental impacts of the funds" are "equitable."[7] As a result of this provision, GAO has undertaken engagements to review the IRA provisions and the associated funding, particularly with respect to the first tranche of selected drugs under the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2026.

As the Medicare Drug Price Negotiation Program continues, new expertise will be developed and honed to improve the processes for successful negotiations in the future. To build on this important work, examining the ongoing implementation of the Medicare Drug Price Negotiation Program to ensure that it further reduces prescription drug prices, saves beneficiaries costs, and drives down federal spending, we ask that GAO review:

1. CMS's negotiation approach and process for the first round of drugs selected under the Medicare Drug Price Negotiation Program for Initial Price Applicability Year 2026, as compared to the second round of drugs selected for Initial Price Applicability Year 2027. When comparing these approaches and processes, we ask that GAO specifically consider:

    a. How successful was CMS at meeting statutory deadlines as required under the IRA, including with respect to the following, broken out by each individual manufacturer and/or drug to the greatest extent possible:
        i. The issuance of guidance and establishment of procedures in a timely manner;
        ii. The establishment and signing of manufacturer agreements;
        iii. The negotiation process, including the submittal of information by manufacturers and the public, initial offer by the Secretary, responses, if any, by the Secretary to a counteroffer from the manufacturer, and adherence to the concluding of the negotiation period; and
        iv. Publication of maximum fair prices established pursuant to the negotiation and the explanation of such prices.

    b. What internal controls—including safeguarding sensitive information and identifying and resolving any ongoing conflicts of interest of personnel involved in negotiations—were put in place by CMS to guide negotiations and how did they change, if so, from negotiations conducted pursuant to

[6] Centers for Medicare & Medicaid Services, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026* (August 2024).

[7] *See* note 4 at Sec. 70004.

Initial Price Applicability Year 2026 as compared to Initial Price Applicability Year 2027?

c. What memorandums of understanding (MOUs) were implemented with other Departments and agencies to ensure compliance and oversight of the Medicare Drug Price Negotiation Program and how did these MOUs change, if so, from negotiations conducted pursuant to Initial Price Applicability Year 2026 to Initial Price Applicability Year 2027? Additionally, what regulations or guidance were issued pursuant to any existing MOUs and how did any such regulations or guidance change, if so, from negotiations pursuant to Initial Price Applicability Year 2026 to Initial Price Applicability Year 2027?

d. With respect to both manufacturer-specific data (as determined under Section 1194(e)(1)) and evidence about alternative treatments (as determined under Section 1194(e)(2)), what processes did CMS use to meet the requirements of Section 1194(e), which requires that CMS "consider" certain factors during negotiations, and how did the analysis of these factors change, if so, from negotiations conducted pursuant to Initial Price Applicability Year 2026 to Initial Price Applicability Year 2027?

e. What processes were used to solicit and receive information from participating drug companies and the public regarding the Medicare Drug Price Negotiation Program and the selected drugs for Initial Price Applicability Year 2026, and did these processes change for selected drugs for Initial Price Applicability Year 2027? Was the information received by CMS for Initial Price Applicability Year 2026 and Initial Price Applicability Year 2027 made publicly available or subject to a formal docket through a Request for Information (RFI) or other comment period? How did CMS utilize the information received for selected drugs for Initial Price Applicability Year 2026 and Initial Price Applicability Year 2027?

f. How did CMS allocate staff resources, which officials conducted negotiation proceedings or were briefed on the negotiation proceedings, and were there staffing changes in terms of expertise, background, or leadership levels from negotiations conducted pursuant to Initial Price Applicability Year 2026 to Initial Price Applicability Year 2027?

Thank you for your attention to this important matter. If you or your staff need additional information, please contact Jacquelyn Bolen with the Energy and Commerce Committee at jacquelyn.bolen@mail.house.gov, Daniel Foster with the Education and Workforce Committee at daniel.foster@mail.house.gov, and Sarah Levin with the Ways and Means Committee at sarah.levin@mail.house.gov.

Sincerely,

Frank Pallone, Jr.
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