U.S. GOVERNMENT ACCOUNTABILITY OFFICE

441 G St. N.W.
Washington, DC 20548

October 19, 2023

The Honorable Brett Guthrie
Chair
The Honorable Anna Eshoo
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

The Honorable Robert E. “Bob" Latta
House of Representatives

Subject: Responses to Questions for the Record; Hearing Entitled *“Examining Policies to Improve Seniors’ Access to Innovative Drugs, Medical Devices, and Technology.”*

This letter responds to your October 10, 2023 request that I address questions for the record related to the Subcommittee’s September 19 hearing. My responses to the questions are based on GAO’s previous work and knowledge on the subjects raised by the questions.

If you have any questions about the responses to your questions or need additional information, please contact me at (202) 512-7114 or DickenJ@gao.gov

John E. Dicken
Director, Health Care

Enclosure

Additional Questions for the Record
Subcommittee on Health
Hearing on
"Examining Policies to Improve Seniors' Access to Innovative Drugs, Medical Devices, and Technology."
September 19, 2023

Mr. John E. Dicken, Director, Health Care, Government Accountability Office

The Honorable Robert E. Latta (R-OH)

1. **Fiscal sanity is something that appears to have disappeared in the halls of Congress. I noted in your testimony today that your September report noted that plan sponsors preferred rebated brand-name drugs over lower-cost alternatives.**

    a. **I am concerned that this practice leads to higher beneficiary costs. Can you share more about the recommendation to have CMS monitor the effects of rebates on Part D plan sponsor formulary design?**

    In our September 2023 report, GAO noted that while plan sponsors use rebates to lower beneficiary premiums, cost sharing for certain beneficiaries could increase to the extent that rebates encourage plans to place higher-gross-cost, highly rebated drugs on their formularies over lower-cost alternatives.[1] Specifically, the cost sharing for beneficiaries who use these higher-gross-cost, highly-rebated drugs could be higher than it would be if plans had placed lower-cost alternatives on their formularies. This is because rebates do not affect beneficiary cost-sharing, as cost-sharing is based on the cost of a drug prior to plans receiving rebates. GAO found that beneficiaries paid four times more than plan sponsors for 79 of the 100 most-rebated drugs in 2021—$21 billion compared to $5 billion.

    The Centers for Medicare & Medicaid Services (CMS) currently conducts a clinical review of formularies to ensure they meet program requirements, but does not consider rebate information. GAO recommended that CMS monitor the effects of rebates on Part D plan sponsor formulary design because doing so would provide CMS, Congress, and others additional insight on the extent to which rebates' influence on formularies could discourage enrollment of certain beneficiaries. This monitoring would also provide CMS with important information as a number of provisions under the Inflation Reduction Act of 2022—including those related to drug price negotiation for selected high-cost drugs and limits on beneficiary out-of-pocket spending—may change rebate incentives and change the effects rebates have on formulary design and spending.

    b. **Knowing that the Medicare program has consistently been featured on the GAO "high risk list" can you further elaborate on GAO policy recommendations that would address longstanding fiscal challenges for**

[1]See GAO, *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending*, GAO-23-105270 (Washington, D.C.: Sep. 5, 2023).

the Medicare program while maintaining patient access to medical innovation?

GAO designated Medicare as a high-risk program due to its size, complexity, effect on the federal budget and health care sector, and susceptibility to mismanagement and improper payments. In 2022, the Medicare program spent an estimated $940.4 billion—about 15 percent of federal spending—to provide health care services for approximately 65 million elderly and disabled beneficiaries. Spending is expected to increase significantly over the next decade as the U.S. population ages and more individuals begin receiving Medicare benefits. Further, the Medicare Hospital Insurance Trust Fund is projected to be depleted in 2031.

Implementing GAO's recommendations focused on the Medicare program could improve the fiscal sustainability of the program. For example:

- GAO recommended in December 2015 that Congress consider directing the Secretary of HHS to equalize payment rates between settings for certain services such as evaluation and management office visits.[2] GAO reported in 2015 that Medicare was likely paying more than necessary for these office visits because the program pays more for these services when performed in hospital outpatient departments than when the same service is performed in physician offices. Equalizing payment rates as GAO recommended could prevent any shift of services from lower paid settings to the higher paid hospital outpatient department setting from increasing costs for the Medicare program and beneficiaries. The Bipartisan Budget Act of 2015 partially addressed our recommendation as it limits certain providers from billing at higher hospital outpatient department rates. However, because this Act does not affect many providers, Medicare and its beneficiaries will continue to pay more than necessary for evaluation and management services. Fully implementing this recommendation could yield over $100 billion in estimated savings to the Medicare program.

- GAO recommended in January 2012 that the Administrator of CMS take steps to improve the accuracy of the adjustment made for differences in diagnostic coding practices between Medicare Advantage (MA) and traditional Medicare; GAO considers this recommendation a high-priority for CMS.[3] CMS applied the statutory minimum adjustment to MA payments for calendar year 2024 and has also made other changes to its methodology for calculating the diagnostic coding adjustment to improve its accuracy (such as excluding diagnosis codes that were differentially reported in MA and traditional Medicare). However, CMS has not modified its methodology to, for example, incorporate more recent data and account for all relevant years of coding differences, which would better ensure an accurate adjustment in future years. The inaccuracy of this adjustment was projected to result in an estimated $23 billion in excess payments to MA plans in 2023, according to the

[2] GAO, *Medicare: Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform*, GAO-16-189 (Washington, D.C.: Dec. 18, 2015).

[3]See GAO, *Medicare Advantage: CMS Should Improve the Accuracy of Risk Score Adjustments for Diagnostic Coding Practices*, GAO-12-51 (Washington, D.C.: Jan. 12, 2012), and *Priority Open Recommendations: Department of Health and Human Services,* GAO-22-105646 (Washington, D.C.: May 26, 2022).

Medicare Payment Advisory Commission. Fully implementing our recommendation could save the Medicare program billions of dollars annually.