Co-Sign Bipartisan Letter to HHS on Proposed Changes to 340B Drug Discount Program

Sending Office: Honorable Doris O. Matsui
Sent By: Jackie.Weinrich@mail.house.gov

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Sign on here: QUILL LINK

Deadline: September 5, 2025

Leads: Reps. Doris Matsui (D-CA), Dusty Johnson (R-SD), Debbie Dingell (D-MI), Tracey Mann (R-KS)

Endorsements: 340B Health, American Hospital Association, ASHP

Dear Colleague,

Please join Representatives Doris Matsui, Dusty Johnson, Debbie Dingell, and Tracey Mann in sending a bipartisan letter to HHS Secretary Kennedy expressing concern about the recently announced 340B Rebate Model Pilot Program.

The 340B Drug Discount program offers a lifeline to the neediest and most underserved patients by requiring pharmaceutical companies to provide drugs at discounted prices to specified clinics and hospitals. The rebate model would reverse over three decades of precedent by changing the program from an up-front discount to a retroactive rebate. This will require safety-net providers to float significant amounts of cash to purchase needed drugs in hopes of a rebate being paid later. In addition, the rebate model gives manufacturers control over whether 340B claims will be approved or denied – providing another avenue for lost revenue for safety-net providers. These changes threaten 340B providers' ability to provide care and to keep their doors open to serve low-income communities.

The letter urges HHS to abandon the Rebate Model Pilot Program and requests a response to questions on the administration of the model, including HHS's oversight plan for the model, legal authority, conflicts of interest, administrative burden for entities and HHS, and evaluation criteria.

If you would like to sign on, please use this QUILL LINK. For any questions, please reach out to Jackie Weinrich in Rep. Matsui's office (Jackie.Weinrich@mail.house.gov) or Sydney Powers in Rep. Johnson's office (Sydney.Powers@mail.house.gov).

Sincerely,

DORIS MATSUI
Member of Congress

DUSTY JOHNSON
Member of Congress

DEBBIE DINGELL
Member of Congress

TRACEY MANN
Member of Congress

FULL LETTER TEXT:

Dear Secretary Kennedy,

We, the undersigned members of Congress, write to express our concerns regarding the recently announced 340B Rebate Model Pilot Program. As the Department of Health and Human Services (HHS) notes, this change would "fundamentally shift how the 340B Program has operated for over 30 years." Congress intended the 340B Program to enable the nation's safety-net providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. An unchecked rebate model would severely undermine that purpose. We urge you to abandon the Rebate Model Pilot Program, or if the program must move forward, to proceed with the utmost caution and impose stronger guardrails to ensure the 340B program is not entirely dismantled.

As HHS is aware, last year, several multinational drug manufacturers—Bristol Myers Squibb (BMS), Eli Lilly, Johnson & Johnson (J&J), Novartis, and Sanofi—attempted to unilaterally impose rebate models on certain covered entities and drugs, despite a clear lack of statutory authority. We are grateful to the Health Resources & Services Administration (HRSA) for its swift and consistent enforcement efforts blocking manufacturers' unlawful attempts to restructure the program without Secretarial approval. HRSA's interpretation and enforcement against the rebate models were upheld by the U.S. District Court in the District of Columbia.[1]

We are concerned that HHS's pilot program will severely damage community health centers, safety net hospitals, and other providers that rely on the 340B program to provide comprehensive, quality services to their patients and communities.

The rebate model pilot program will require all covered entities to purchase drugs on the CMS Medicare Drug Price Negotiation Selected Drug List at the wholesale acquisition cost – the highest sticker price that manufacturers offer, which is rarely actually paid by purchasers in the health care system. This will require 340B providers to float significant amounts of cash to drug companies in hopes of a rebate being paid. Further, these drugs, despite their prices being reduced through price negotiation, are still some of the costliest drugs in the Medicare Part D program. If the entire 340B program moved to a rebate model, the average Disproportionate Share Hospital in the country would be forced to float an estimated $72.2 million to manufacturers annually.[2]

This is a cost most 340B providers, many of whom are experiencing financial instability, simply cannot afford. 340B hospitals already have substantially lower—negative on average—operating margins compared to non-340B hospitals. And in 2023, nationally, nearly half of health centers had negative operating margins; overall net margins were 1.6 percent.[3] These changes threaten 340B providers' ability to provide care and to keep their doors open to serve low-income communities.

In addition, we are concerned that this rebate model will be used by manufacturers as a backdoor to recoup their own profits that may have been lost as a result of lowering prices through the Medicare Drug Price Negotiation Program (MDPNP). This was never Congress's intent in establishing the MDPNP. While we appreciate HRSA's attempts to place guardrails around this pilot program, these guardrails will not be sufficient to prevent aggressive tactics by manufacturers to deny claims and siphon money away from providers and their patients.

Finally, as we have affirmed on multiple occasions, we continue to believe that the rebate approach contravenes Congressional intent in establishing the 340B program and over three decades of precedent set by HRSA that distinguishes rebates and retroactive discounts from upfront 340B discounts.[4]

As such, we urge you to cancel the pilot program. However, if HHS chooses to continue with this pilot, we request answers to the following questions, no later than September 15, 2025:

1. HHS notes that this pilot would "fundamentally shift how the 340B Program has operated for over 30 years." Yet the timeline for implementation of this pilot leaves little room for meaningful covered entity input, while mandating significant additional costs for those entities.
    a. What legal authority does HHS cite to support a 30-day public comment period, after which HHS is "under no obligation to respond or act on" any comments, in making this significant change?
2. What is HHS's justification for imposing such significant changes on a rushed timeline, including only 30 days for public comment, one week to review public comments including input from 340B providers who have otherwise been uninvolved in the process, and four weeks to review manufacturers' proposed plans?
3. How will the Information Technology (IT) platform be selected to ensure reduced administrative and logistic burden for covered entities, while avoiding any conflicts of interest? Will manufacturers be required to consider input from covered entities?
4. With regards to the determination of claims' validity and issuance of rebates under the program:
    a. What are HHS's plans for ongoing audits and oversight to determine whether manufacturers are appropriately approving claims and issuing rebates in a timely manner?
    b. If manufacturers do not pay rebates within 10 days of receiving covered entities' submissions of data as required by the rebate model parameters, inappropriately deny entities' claims, or otherwise use this pilot program to abuse the 340B Program, what enforcement tools will HHS use against noncompliant manufacturers? Will there be any special expedited procedures to allow covered entities to use the administrative dispute resolution (ADR) process to contest invalid manufacturer actions?
    c. What additional criteria do HHS envision as permissible and impermissible for manufacturers to use as grounds to deny claims? For example, will HHS permit manufacturers to deny rebates by alleging that providers are not complying with the manufacturer's unilaterally imposed restrictions on contract pharmacy?
5. The guidance states that "no additional administrative costs of running the rebate model shall be passed onto the covered entities." How will HHS ensure this includes all administrative costs related to this rebate model pilot program, including labor costs and the costs of contesting denials? What enforcement mechanism will ensure that manufacturers pay all such costs in a timely manner?
6. The announcement notes that manufacturers can apply to participate for a "minimum of 1 year."
    a. What is the maximum amount of time HHS will permit manufacturers to run these rebate models?
    b. Does HHS plan to re-evaluate the rebate model after one year to assess whether it will continue to permit manufacturers to remain in these rebate arrangements?
7. HHS states that it will evaluate "data and reports received from the participating manufacturers on the effectiveness of the model and covered entity and other stakeholder feedback," after which HHS may consider expanding the rebate model to other drugs purchased under the 340B program.
    a. Which performance measures will the agency use to measure effectiveness?
    b. How will the ability of covered entities to provide care to underserved patients, as well as other feedback from covered entities, be weighed in the assessment of effectiveness?
    c. Will the agency commit to make public the results of the assessments it conducts of the model's effectiveness?
    d. On what basis would the agency decide to increase the number of drugs subject to rebates by adding drugs with negotiated prices coming into effect in 2027 under the MDPNP?
    e. On what basis would the agency determine to include drugs that are not under the MDPNP?
8. For many years and across several administrations, HHS has requested increased resources for implementation and oversight over the 340B Program. Yet this pilot program would significantly increase administrative burden for HHS staff, whose new responsibilities will include reviewing manufacturers' applications and resolving any issues within 30 days from receipt, performing audits and ADR for any deviations from program guidelines, addressing issues raised by covered entities if there are issues with rebate delays and denials, and fielding any other administrative or logistical issues emerging through implementation of the rebate model. What is HHS's plan to implement such a pilot program while maintaining regular oversight of the 340B program?

[1] “Eli Lilly and Company et al v. Robert F. Kennedy et al.” (2025) https://sponsors.aha.org/rs/710-ZLL-651/images/2025-05-15_340B_Rebate_Models_Ruling

[2] Manufacturer 340B Rebate Models Threaten Safety-Net and Rural Hospitals and Would Harm Patients, 340B Health (2025). https://www.340bhealth.org/files/340B_Health_MANUFACTURER_340B_REBATE_MODELS_Report.pdf

[3] Federman, Sara; Bryan, Alexandra; Horstman, Celia; Lewis, Corinne. Community Health Centers Are Serving More Patients Than Ever, but Financial Challenges Loom Large, The Commonwealth Fund (2024). https://www.commonwealthfund.org/blog/2024/community-health-centers-are-serving-more-patients-ever-financial-challenges-loom-large

[4] Final Notice on Entity Guidelines, 59 Fed. Reg. 25112; Notice on Initial Guidance, 58 Fed. Reg. 27291, 27292.

Related Legislative Issues

Selected legislative information: HealthCare