Mailing Address:
ADAP Advocacy
PO Box 846
Nags Head, NC 27959

Office Address:
1630 Connecticut Ave, NW
Suite 500
Washington, DC 20009

CEO:
Brandon M. Macsata
Washington, D.C.

adapadvocacy.org

June 25, 2025

The Honorable Russell Vought
Director, Office of Management and Budget (OMB)
725 17th St., NW
Washington, DC 20503

RE: RIN: 0906-ZA14 | 340B Rebate Guidance

Dear Director Vought:

We are writing to express our strong support for the proposed drug manufacturer rebate model for the 340B Drug Pricing Program, as the program, long mired in opacity, must be made transparent. As a patient advocacy organization, we are *very strong* proponents of a robust 340B Program, and the implementation of the drug manufacturer rebate model strengthens the program by instilling greater accountability and transparency. Rebates will provide the platforms and the data necessary to understand, without obfuscation or manipulation, whether needy 340B drug patients receive the benefit of the 340B price.

The ADAP Advocacy mission is to promote and enhance the AIDS Drug Assistance Programs (ADAPs) and improve access to care for persons living with HIV/AIDS. ADAP Advocacy collaborates with stakeholders to raise awareness, provide patient education programs, and promote community collaboration.

The 340B Program is intended to help uninsured and underinsured patients access affordable healthcare. Some covered entities, such as AIDS Drug Assistance Programs, which already use a rebate mechanism, operate in accordance with Congress's intent. However, that is not the case for most 340B hospitals, which dominate the program, receiving 80% of the program's revenues and profits.

340B profits are now $80 billion a year, yet 31% of the U.S. population remains uninsured or underinsured. Although the 340B program grew 1,000% from 2011 to 2023, charity care provided by 340B hospitals actually dropped 18%. 340B hospitals provided only 2.15% of their spending towards charity care in 2022. That is an abysmally low commitment to patients in need, even as they reap billions in profits from the 340B program.

ADAP Advocacy's 340B Map drills down on the problem, as evidenced by the example of Sutter Valley Hospitals, based in Sacramento, California, which saw a 258.94% percent change in revenues from pre-340B eligibility to present. Yet, the hospital system's charity care declined by 72.45% over the same period. Perhaps more egregiously, over that same period, there was a 1,133.42% increase in its CEO's compensation.

Another example is Yale New Haven Hospital (YNHH), located in New Haven, Connecticut. YNHH's CEO saw a hefty 1,421.15% increase in executive compensation between 2003 and 2021, largely attributed to the hospital system's 450.72% percent change in revenues over the same period. Sadly, YNHH's level of charity care didn't keep pace with its explosive growth in executive compensation and revenues. Although its charity care percentage marginally increased, its rate of profit increase was 33 times its increase in charity care.

The 340B Program has morphed from a program designed to assist low-income patients into a revenue stream for healthcare providers. This growth has largely benefited providers, with little patient benefit, particularly at the pharmacy counter. Was this program *really* designed to fund lavish executive compensation packages at the expense of patients who are required to pay out-of-pocket to help fund that compensation and the billions in 340B profits?

Some concerning examples in HIV care include the Sarasota, Florida-based CAN Community Health. Its executive compensation increased by 1,088.94% since 2010. Among STD Clinics, a disturbing example of this provider-patient misalignment is Nashville, Tennessee-based Music City PrEP's CEO's four-year pay increase of 1,760.44%. The covered entities that these executives lead oppose any meaningful reforms to the 340B program.

Sadly, 340B contract pharmacies are even worse than 340B hospitals at providing financial assistance to patients receiving drug therapy—they can only be shown to provide assistance on *only* 1.4% of branded prescriptions. Patients' drug needs generate billions for 340B hospitals, but patients do not share in 340B pricing when they go to the pharmacy counter to pick up their medications. And they don't even know how they are being mistreated because there is no transparency. To justify the billions in subsidies generated from 340B patients, many of whom pay substantial sums out of their own pockets to help fund those massive subsidies, the program should allow patients to understand whether their provider is sharing any of its heavily reduced prices with them.

The proposed manufacturer rebate model should now be permitted for all covered entity types, as it can bring transparency to all stakeholders. The rebate system can finally allow patients to see if they are getting any benefit from the pricing at the pharmacy counter.

This rebate-based approach is already being used with State AIDS Drug Assistance Programs (ADAP), which also operate as covered entities under the 340B Program. Consistent with our very positive ADAP experience, it will not be burdensome for covered entities. In fact, most 340B observers consider ADAPs as the "gold standard" among all covered entities because of the accountability and transparency standards associated with their participation in the program, which is substantially a consequence of the use of rebates.

Any claim that allowing a manufacturer rebate model is too burdensome is inaccurate and, in our view, disingenuous.

Why?

- Initial Non-Discount Prices: This is the standard situation with State AIDS Drug Assistance Programs, and it has not prevented the substantial growth in those programs and the funding they provide for patient care, including patient assistance at the pharmacy counter. More broadly, providers receive up to 30 net days from their distributors after receipt of their drugs to pay for them. Payment of rebates in 7-10 days, as already committed to by drug makers, will, with even reasonably good inventory management, typically mean that the rebate will be paid to the provider before the provider must pay for the underlying drug.

- Claims Data: Third-party administrators already have all the required data and can easily transmit it to support a rebate model. This is simply the standard data that covered entities already collect and must use for billing purposes.

- Denials: Some covered entities speculate that manufacturers will deny some claims for rebates. However, manufacturers will face huge penalties if they fail to pay when required. When some covered entities say this is an issue, they, frankly, are tacitly admitting that they engage in duplicate discounts and diversion. The "good actors" simply do not object to rebates on this basis.

In opposing 340B rebates paid in 7 to 10 days or less, the Secretary adopts a position that is fundamentally at odds with the payment window he has set (and found entirely acceptable) in the Medicare negotiated price context under the Inflation Reduction Act (IRA), which is 14 days. The Health Resources and Services Administration's refusal to recognize *faster* 340B rebate payments cannot be squared with the Secretary's IRA standard for "prompt" payment (CMS, 2024). That arbitrary and capricious inconsistency is a violation of the Administrative Procedure Act, 5 U.S.C. §555, *et. seq*., and even more troubling because HRSA's position will undermine IRA implementation and harm patients.

As patient advocates, we want to be clear about this. There are currently no alternatives to the rebate model in attempting to implement the IRA. The contracting, payment, financial, operational, technical, data, system, and testing requirements would have been a challenge even if the decision to pursue an alternative had been taken when the IRA was passed in 2022. It is hopeless now. Manufacturers are, as the government itself has effectively conceded, the ones going to fix this fundamental challenge to the IRA--or implementation will inevitably suffer.

The need for transparency is acute because unsuspecting patients are losing what little access, they have had to charity care even as 340B expands and expands, bringing additional billions to covered entities and for profit "middlemen" A rebate model can finally allow patients to understand whether they are receiving any part of the benefit of 340B pricing at the pharmacy counter. All too often, paying cost-sharing amounts based on provider charges that are wildly higher than their 340B providers' actual costs, the patients who generate billions in 340B profits for hospitals are excluded from any benefit of that pricing when it comes time to pay out-of-pocket at the pharmacy counter.

As you continue your review of E.O. 12866, it is essential to remember that *only* patient advocacy organizations can effectively represent the needs of patients. It is for that reason that ADAP Advocacy **supports this 340B rebate model for the 340B Program**.

Respectfully submitted,

Brandon M. Macsata
CEO

cc: Dan Klein (OIRA)
William Sarraille, ADAP Advocacy Special Counsel