IMPACT OF THE INFLATION REDUCTION ACT ON THE 340B PROGRAM

Northern California HIV/AIDS Policy Research Center | October 2023

KEY TAKEAWAYS

1. The **340B program** provides a revenue source for eligible health facilities serving safety net populations through additional reimbursement for medications. The facility purchases the medication at a discounted rate but receives a higher amount in reimbursement and can use those additional funds to support programs and services for underserved patients.
2. The **Inflation Reduction Act of 2022** included several provisions to reduce spending on prescription drugs. **One provision introduced a new penalty for escalating drug costs above inflation.** [1, 2]
3. Modeling conducted by our policy research center suggests that **340b revenue may be decreased by approximately 50%** for HIV treatment and prevention medications due to changes in drug pricing from the Inflation Reduction Act.

BACKGROUND

340B CEILING PRICE: KEY CONCEPT

The ceiling price is the maximum price that drug manufacturers can charge a facility for a 340b-covered drug.

First, the average manufacturer price (AMP) is calculated for a specific medication.

The AMP is then reduced by a set "rebate percentage" (23.1% for brand name drugs; 13% for generic).

This amount is then further reduced by an **inflation penalty** for drugs that have prices that rise faster than inflation.

➤ **This final number then represents the ceiling price.**

SERVICES PROVIDED BY THE 340B PROGRAM

340b revenue is flexible and used by many facilities to provide services not well supported by traditional insurance[3] such as:

- home visits
- transportation services
- pill boxes
- mobile clinics
- healthy food programs

CHANGES TO INFLATION PENALTIES

➤ Previously, inflation penalties have been built into the 340b ceiling prices and to manufacturer rebates to state Medicaid programs, but not for Medicare.

➤ However, with the Inflation Reduction Act, there is now a rebate to Medicare from any manufacturer whose drug price rises faster than inflation. The manufacturer must pay this rebate to the government. The cost equals the amount that the drug's cost exceeds inflation and is calculated for each unit of medication sold in Medicare.

SIGNIFICANCE OF THE NEW INFLATION REBATE IN MEDICARE

➤ Medicare is a large payer of prescription drugs. The previous inflation penalties in the 340b program and Medicaid did little to contain manufacturer costs. However, the new inflation penalties will likely have a significant impact on drug pricing.

➤ **Many HIV medication manufacturers have drugs with prices rising faster than inflation.**[4] The new inflation penalty may curb these rising costs.

FINDINGS

The 340b program's design creates a counterintuitive situation for clinics and hospitals. **Lower drug prices mean less 340b revenue because they lead to a smaller difference between the drug cost and reimbursement.**

The examples below illustrate how a clinic or hospital receives funds through the 340b program and shows the potential difference in revenue for generic versus brand name drugs, as well as the impact of inflation-adjusted pricing.

Example 1: Differences in clinic revenue for generic vs. brand name medication

	Price by Inflation	AMP/unit	Base Reduction	Inflation Penalty	Ceiling Price	Surplus to Clinic
Drug A (generic)	$1.24	$0.84	$0.11	$0.00	$0.73	**$0.11**
Drug B (brand)	$48.24	$59.67	$13.78	$11.43	$34.46	**$25.21**

Example 1 shows a substantial difference in clinic revenue for expensive, brand name drugs versus generic drugs in the 340b program.

Assuming one pill daily regimens, the annual 340b funds for the clinic would be:

- $40.15 for Drug A (generic)
- $9,201.65 for Drug B (brand)

Example 2: Differences in clinic revenue for one drug when priced over vs. with inflation

	Price by Inflation	AMP/unit	Base Reduction	Inflation Penalty	Ceiling Price	Surplus to Clinic
Drug B (brand) priced over inflation	$48.24	$59.67	$13.78	$11.43	$34.36	**$25.21**
Drug B (brand) priced with inflation	$48.24	$48.24	$11.14	$0.00	$37.10	**$11.14**

Example 2 shows how adjusting drug prices to align with inflation results in decreased 340b revenue.

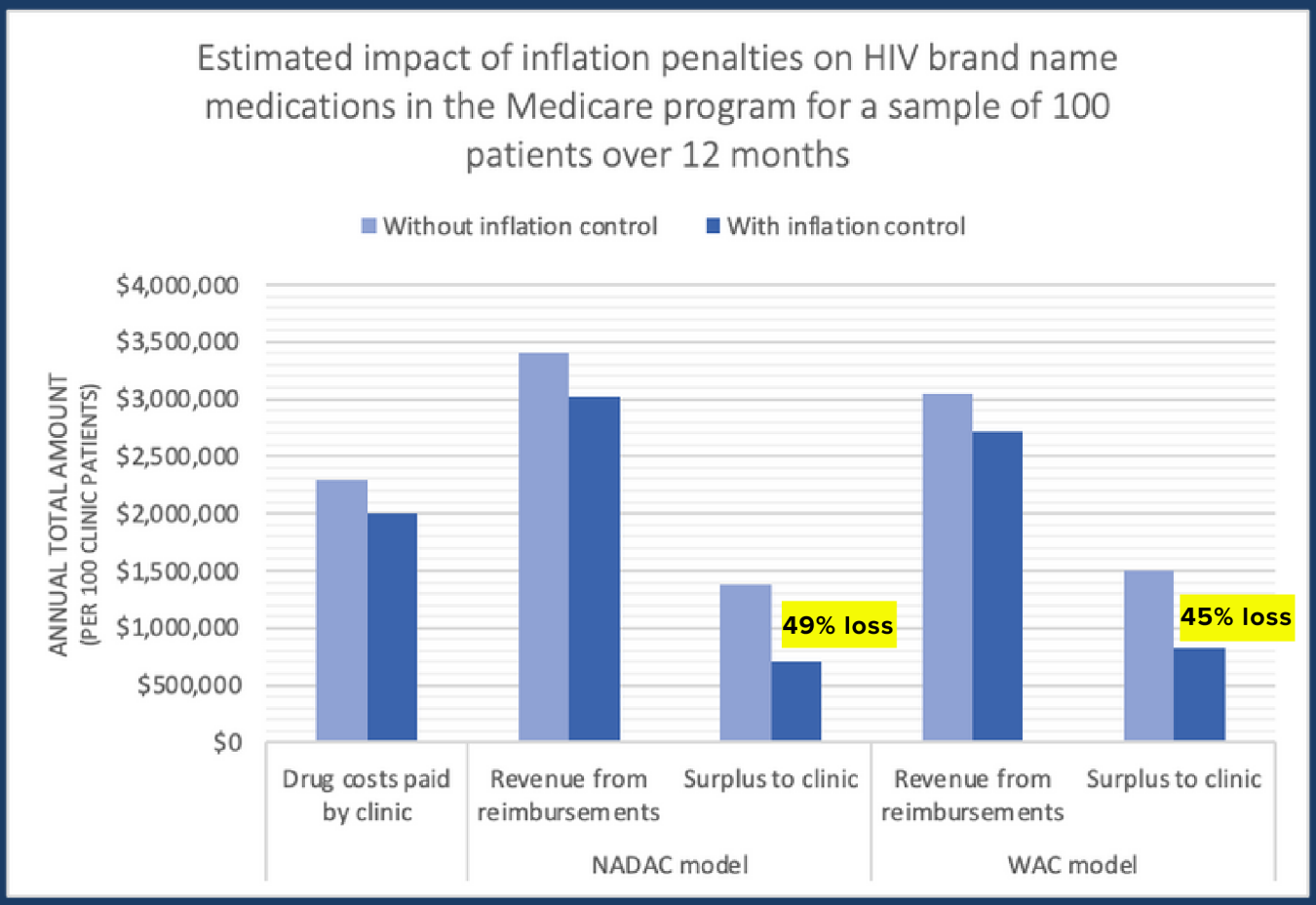
Assuming one pill daily regimens, the annual 340b funds for the clinic would be:

- $9,201.65 for Drug B priced over inflation
- $4,066.10 for Drug B priced with inflation

TABLE LEGEND

- **Price by inflation** = expected price of drug per unit, if its price escalations were in line with the inflation rate.
- **AMP/unit** = average manufacturer price per unit of medication (typically, one unit is one pill). Usual reimbursement rates from insurers and other payer sources would be based in part on the AMP.
- **Base reduction** = set percentage reduction for generic (13%) or brand name drugs (23.1%). Used to calculate the 340b ceiling price.
- **Inflation penalty** = excess price in AMP compared to price by inflation. Used to calculate the 340b ceiling price.
- **Ceiling price** = AMP - base reduction - inflation penalty. This is the maximum amount an eligible health care entity would pay to purchase the covered drug through the 340b program.
- **Surplus to clinic** = AMP/unit subtracted by ceiling price. This is the amount of revenue generated by the 340b program from one unit of the drug. It assumes the health care entity's reimbursement from insurance or other source would be equal to the AMP.

Table 2 from the previous page reflects a typical example based on our models, which estimate an overall 45-50% reduction in surplus funds to clinics through 340b revenue from HIV treatment and prevention medications if drugs are priced to align with inflation.



*Includes all brand drugs (e.g., Biktarvy, Descovy, Truvada, and others)
*Excludes Mavyret, Cabenuva, Epclusa, Harvoni, whose prices have not increased faster than inflation
*WAC-estimated NADAC, Mean – 20% Trimmed, n=20. Trimmed mean is used to include expensive new drugs while reducing their impact as outliers.

Methods Notes:

- Two models were created and compared. Both yielded similar results as shown in the figure above. Since the AMP is proprietary, other sources had to be used to estimate it. One model used the National Average Drug Acquisition Costs (NADAC) to estimate the AMP, and the other model used the Wholesale Acquisition Costs (WAC) to estimate the AMP. The WAC model includes a greater number of medications as an official NADAC estimate was not available for all HIV drugs.
- Costs were considered for both antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP).
- The data are presented as a sample of revenue that would be obtained by a clinic for every 100 patients. The models were constructed by first calculating the ceiling price for each individual drug. The ceiling prices and revenues were then multiplied by the number of units (a single dose) in a prescription to attain the prescription ceiling price and revenues. The prescription prices and revenues were averaged and then multiplied by 12 to find the average prices and revenues for a single patient over a year. Finally, the average price and revenue per patient was multiplied by 100 patients.
- Assumptions and Limitations
  - The models assume that reimbursement from insurance equals the non-340b program average manufacturing prices.
  - Modeling does not account for changes in prescribing patterns, variations in current prescribing patterns across different facilities, discriminatory pricing, and non-compliance by drug companies.

REFERENCES & ACKNOWLEDGEMENTS

1. Kaiser Family Foundation. Jan 2023. Explaining the Prescription Drug Provisions in the Inflation Reduction Act.
2. Arad N & McClellan M. Dec 2022. Drug Pricing Reform in the Inflation Reduction Act: What are the implications? *Health Affairs.*
3. Association of American Medical Colleges. March 2019. 340B helps the most vulnerable patients.
4. McCann N, et al. Feb 2020. HIV Antiretroviral Therapy Costs in the US, 2012-2018. *JAMA Internal Medicine.*

This work was supported by the California HIV/AIDS Research Program (CHRP) grant #H21PC3238, PI Arnold.

CALIFORNIA HIV/AIDS POLICY RESEARCH CENTERS