Legal Backgrounder

Washington Legal Foundation
Keeping Free Enterprise Free

Vol. 41 No. 18 November 19, 2026

Does the Federal 340B Rebate Pilot Make Patient Assistance Impossible?

by William Sarraille and Chuan Sun

The 340B Drug Program is at the threshold of implementing a major reform. After decades of mounting concern expressed by critics about its fraud and abuse risks, a pilot is scheduled to be introduced on January 1, 2027 designed to bring transparency to this rapidly expanding program.[1] But hospital associations and other opponents of the Pilot contend it will prevent 340B covered entities from offering patient assistance, including free or discounted drugs, to patients in need.[2] We undertook a data-driven test of that claim using a model that we have developed to test the impact of the Pilot empirically.[3] We find no evidence to conclude that the Pilot will adversely affect charity care or patient assistance in any material way.

Background

Under the 340B program, drug makers are obligated to provide low prices on their drugs as a condition of receiving Medicare and Medicaid coverage for their drugs. The covered entities that receive those drugs are then able, typically, to seek full reimbursement from third party payers, like commercial payers, employers, and Medicare, for those low-priced drugs. The difference between the low acquisition price and the reimbursement value of the drugs are called "spread" or "margin." The acquisition price of 340B drugs was $100 billion in 2025. Two analyses of the resulting spread have been undertaken. One, measuring the reimbursement value of the drugs by examining their list prices, indicates that the spread reached $80 billion in 2025; the other measured the spread at $144 billion.[4]

Program Basics. Because the prices under 340B are so low, Congress provided that it is unlawful for a 340B drug to be diverted to any person or entity not a patient of the covered entity entitled to the price.[5] Similarly, it is unlawful to claim a duplicate 340B price on a drug for which a Medicaid rebate has been paid.[6]

---

[1] *See* HRSA, "Notice Regarding 340B Rebate Model Pilot Program" (HRSA Rebate Notice), 91 Fed. Reg. 48,883-01, 48,886 (Aug. 3, 2026).

[2] *See, infra*, at 2-3.

[3] C. Sun *et al.*, *How Will a Rebate Model Impact Cash Flow in the 340B Drug Pricing Program?* 4 (IQVIA White Paper, Dec. 2, 2025); R. Martin *et al.*, *Do 340B Rebates Create a Significant Financial Burden for 340B Providers?* 2–3 (IQVIA White Paper, Apr. 2026).

[4] HRSA Rebate Notice, 91 Fed. Reg. at 48,884 (approximately $100 billion in 340B purchases); R. Martin *et al.*, IQVIA, *The Size and Growth of the 340B Program in 2025*, 3 fig.1 (June 4, 2026) (list price value of program, a measure of reimbursement value, is approximately $180 billion); *but see* E. Blalock, *et al.*, "The Size of the 340B Program: Patient and Payer Spending on Drugs Purchased Through the 340B Program Reached $244 Billion in 2025," Berkeley Research Group (Oct. 1, 2025). Consistent with our conservative methodology here, we will use the lower figure for this analysis.

[5] 42 U.S.C. §256b(a)(5)(b).

[6] 42 U.S.C. § 256b(a0(5)(A)(i); 42 U.S.C. § 1396r-8(j).

William Sarraille is Professor of Practice, University of Maryland Francis King Carey School of Law. **Chuan Sun** is a Data Science Manager with IQVIA. *The views expressed in this article are those of the authors, not their employers.*

To date, the low prices provided by manufacturers under 340B have typically been provided as an upfront discount. Using that mechanism, the program has grown by 1,900% in purchases and 700% in spread.[7] Multiple government reports have expressed serious concerns about the fraud and abuse risks of the program, sometimes attributing those concerns, in part, to features of the discount model.[8] At a practical matter, a discount, once extended under the program, is almost impossible to claw back given the limitations that the program imposes on drug makers.

The issue is complicated further by the use of contract pharmacies. Covered entities often use contract pharmacies to leverage 340B drugs and profits. Under the contract pharmacy model, covered entities claim 340B prices on drug dispenses made by pharmacies that the 340B entities neither own nor operate. Contract pharmacy arrangements often involve large for-profit pharmacy chains, and they may be in affluent areas, sometimes thousands of miles away from a 340B covered entity's service area. Contract pharmacy arrangements rose dramatically from 2,000 in 2010 to nearly 130,000 in 2021.[9] Between $17 and $23 billion in 340B revenues are paid each year to contract pharmacies and the third-party administrators that are often affiliated with them.[10]

The Pilot. After years of consideration, the Health Resources and Services Administration (HRSA), the agency charged with oversight over 340B, decided to initiate a Pilot intended to bring a measure of transparency to this rapidly expanding program.[11] Under that Pilot, drug makers would receive data and a short 10-day window to decide whether to pay the 340B price on drugs also subject to Medicare prices negotiated by the government.

Under the Inflation Reduction Act (the IRA), the Medicare program can condition Medicare coverage on a drug maker agreeing to substantial price cuts.[12] The price that emerges out of this process is called the Medicare Maximum Fair Price or MFP. Under the IRA, drug makers are not required to give an MFP and a 340B price on the same Medicare drug except when the 340B price is lower than the MFP.[13]

The data provided under the Pilot may also be used to address Medicaid/340B duplicates, in addition to MFP/340B duplicates.[14] In prior research, 340B duplicates involving MFP and Medicaid rebates for 2027, the first year of the Pilot, have been calculated to be between $ 9.95 to $13.15 billion.[15]

The Contention. The American Hospital Association (AHA), the Maine Hospital Association, and others have filed suit against HRSA to stop the Pilot. In that lawsuit, they allege that the Pilot will "require reassessment of ... the provision of free and discounted drugs" to needy patients, will "likely shut down" patient

---

[7] These percentages are based on the 340B 2025 purchase and reimbursement value figures discussed in fn. 5 and comparing those to a 2010 baseline. In 2010, 340B involved $5 billion in purchases and roughly $15 billion in list price value, a measure of reimbursement value. *See* Cmty. Oncology All., *COA Prescription for Health Care Reform: A Policy Blueprint for Congress* 12 fig.1 (2025); HRSA Rebate Notice, 91 Fed. Reg. at 48,884; R. Martin *et al.*, IQVIA, *The Size and Growth of the 340B Program in 2025*, 3 fig.1.

[8] *See, e.g.*, HRSA Rebate Notice, 91 Fed. Reg. at 48,887; Staff of H. Comm. on Energy & Com., 115th Cong., *Review of the 340B Drug Pricing Program* 3, 7 (Jan. 10, 2018); U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen., OEI-05-13-00431, Contract Pharmacy Arrangements in the 340B Program, at 2 (Feb. 4, 2014); HRSA Rebate Notice, 91 Fed. Reg. at 48,890 & n.19).

[9] Cong. Budget Off., *Growth in the 340B Drug Pricing Program* (Sept. 2025).

[10] W. Sarraille, *et al.*, "A Look at Middlemen Fees in the 340B Drug Discount Program," *Law360* (Dec. 3, 2025).

[11] HRSA Rebate Notice, 91 Fed. Reg. at 48,885-87.

[12] *Id.* at 48,899.

[13] 42 U.S.C. § 1320f-2(d).

[14] HRSA Rebate Notice, 91 Fed. Reg. at 48,890.

[15] C. Sun *et al.*, *How Large Are 340B/MFP Duplicate Discounts? 3: Discussion*, IQVIA (Oct. 29, 2026) (MFP/340B duplicates are $6.1 to $9.3 billion and Medicaid/340B duplicates are $3.85 billion).

© 2026 Washington Legal Foundation

assistance programs, and will necessitate covered entities to "reduce or eliminate" patient assistance.[16]

Charity Care and Patient Assistance. In the lawsuit, plaintiffs take the position that their members provide substantial charity care and patient assistance. In an amicus brief filed in the AHA challenge, however, some patient groups responded with skepticism to that argument.[17] In expressing that skepticism, those patient groups argued that the literature and available data demonstrate a disconnect between the growth of the 340B program and the provision of free or discounted charity care.

According to the publicly available data, 340B hospitals, which receive 87% of the benefits of the 340B program,[18] provide a low level of charity care that has diminished over time. In 2014, 340B hospitals had an average charity care rate of 3.20%,[19] meaning that for every $100 they spent they devoted just $3.20 to charity care. As the 340B program grew exponentially thereafter, however, 340B hospital charity care was reduced to 2.33% by 2024, a 27% decline.[20] A recent study puts the rate at 2.16%,[21] a 40% decline.[22] These declines have occurred over a period in which 340B spread has risen 700%.[23] The 340B hospital charity care average is below the charity care average for non-340B hospitals.

Prior research also shows that patient assistance is not usually provided to 340B patients receiving their branded drugs from contract pharmacies. Two studies show that between 95% and 98% of 340B contract pharmacy patients using branded drugs did not receive financial assistance on their drugs.[24] To put these charity care and financial assistance numbers into context, 30% of the U.S. population are uninsured or underinsured.[25]

Higher Mark-ups. In addition to concerns about the charity care and assistance available to most 340B patients, concerns have been raised about the ability of 340B hospitals to impose high costs for drugs and other services. Critics contend that 340B hospitals often dominate their local markets, and a number of studies confirm that 340B hospitals are the source of higher costs to patients and payers.[26] 340B provider mark-ups have "increased health care costs for employers, their workers, ... payers, ... state and local governments, ... [and] Medicare and Medicaid."[27] Higher costs to payers mean higher out-of-pocket

---

[16] *American Hospital Association v. Kennedy*, 1:26-cv-00515 (U.S.D.C. Me), Complaint (Oct. 9, 2026), at ¶¶ 107-08.

[17] *American Hospital Association v. Kennedy*, 1:26-cv-00515 (U.S.D.C. Me), Amicus Curiae Motion for Leave to File an Amicus Brief, Exhibit A (Nov. 9, 2026).

[18] HRSA Rebate Notice, 91 Fed. Reg. at 48,900.

[19] *See* Pioneer Institute, "340B Abuse: Hospital Charity Care" (2024).

[20] *Id.*

[21] R. Popovian, *et al.*, The 340B Accountability Gap: Charity Care, Uncompensated Care, and Medical Patient Volume Among 340B and Non-340B Hospitals, Pioneer Institute, No. 296, at 4 (Sept. 2026).

[22] *Id.*; AIR340B, "Charity Care at 340B Hospitals is on a Downward Trend", at 6 (Oct. 2023), https://340breform.org/wp-content/uploads/2023/10/2023-Charity-Care-Report-Final-1.pdf.

[23] *See, supra*, at fn. 7.

[24] R. Martin, *et al.*, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients of Contract Pharmacies?", IQVIA (Sept. 27, 2022); R. Martin, *et al.*, "Do Patients Receive 340B Drug Discounts at the Contract Pharmacy Counter?", IQVIA (July 2, 2025).

[25] *See* Commonwealth Fund, "The State of Health Insurance Coverage" (2024).

[26] *See, e.g.,* Jason Gomberg, *et al.*, "Commercial Payers Spend More on Hospital Outpatient Drugs at 340B Participating Hospitals," *Milliman*, at 2 (costs are 187% higher at 340B hospitals); Gov't Accountability Off., GAO-15-442, Medicare Part B Drugs: "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals", GAO-15-442, at 31 (June 2015), https://www.gao.gov/assets/gao-15-442.pdf (average per beneficiary drug spend 140% higher at 340B hospitals).

[27] S. Zeng *et al.*, *What Is Driving 340B Growth: Utilization or Price?*, 3 Health Aff. Scholar, no. 6, 2025, at 1; Chuan Sun *et al.*, IQVIA, *The Cost of the 340B Program Part 1: Self-Insured Employers* (IQVIA White Paper, Mar. 2024); C. Sun *et al.*, *The Cost of the 340B Program to States*, ISPOR Value in Health, Vol. 28, Issue S1 (May 2025).

© 2026 Washington Legal Foundation

obligations for patients who do not benefit from charity care or other forms of assistance.[28]

Analysis

We decided to put the claim that the Pilot will result in the termination of charity care and patient assistance to an empirical test, given the public health importance of that claim. We did so by using a model that we developed to assess the interest costs associated with the Pilot. That model uses a cash flow analysis to assess the cost of extending patient assistance under the current discount model and comparing those same costs under the Pilot and its rebate mechanism.[29] To be conservative, we apply a clinic, rather than a hospital model, as clinics have higher average borrowing costs.

The Current Discount Model

1). Starting on day 0, the clinic (the CE) currently purchases an MFP drug with a $200 340B price and a Medicare allowable for reimbursement purposes of $400, with a $40 copayment.

2). On day 10, the CE pays the wholesaler $200. As is typical, the CE has payment terms from the wholesaler, meaning the CE does not pay for the drug on the date that it receives it. Covered entities previously urged us to use a payment term of 10 days, on average, which we apply here even though prior research involving interviews with multiple covered entities and the review of public wholesaler contracts established longer payment terms.

3). On day 15, the CE dispenses to a patient in need who cannot pay the $40 co-payment. We applied this parameter because our prior research established that the average inventory turn rate for MFP drugs, given their volume, was shorter than most drugs. We applied 15 days specifically because it represents the mid-point in a 30-day inventory "turn" rate, which was established as reasonable for these drugs, on average. We also modeled the discount and the rebate model up to 30 days, which does not materially change the analysis.[30]

4). On day 15, the CE dispenses the drug and submits its claim to the insurer. It does not ask the patient to pay the $40 copayment given the patient's inability to pay.

5). On day 45, in compliance with a 30-day claims payment mandate that applies to most payers, the plan pays $360, the $400 allowable less the $40 copayment. Faster payment by the plan would improve the financial analysis in both the discount and rebate analyses. Though slower payment would affect it as well, this factor is not dependent on how the 340B price is provided.[31]

To assess the interest costs associated with the discount model, we apply a 12% CE borrowing cost on a per annum basis.[32] The interest cost is $200 * (45 days – 10 days) * 12% / 365 days = $2.30. This is the interest cost on a drug with a $400 list price, a $200 340B price, and a $160 spread between the acquisition cost and its reimbursement value.

Now, let's examine the corresponding scenario under a rebate model.

---

[28] Zeng *et al.*, *supra*, at fn. 27 ("when disproportionate share hospitals ... begin participating in the program, total community benefit spending (including charity care) does not change").

[29] *See, supra,* at fn. 2.

[30] Further, when we apply turn rates that are longer, we apply them to both the discount and the rebate models and that makes that variable not one that affects the relative outcomes in any meaningful way.

[31] We do not consider the value of dispensing fees here, which would improve the financial analysis in both the discount and rebate scenarios.

[32] As our prior research shows, borrowing costs for other covered entities is substantially lower than for clinics, but, consistent with the conservative approach we take here, we apply the higher clinic borrowing cost parameter.

© 2026 Washington Legal Foundation

The Rebate Pilot

1). The clinic now purchases the drug at a list price less any otherwise applicable discounts, which we will ignore here to be conservative.[33] Wholesalers give discounts on branded drugs to lock in purchases of generics and other items. We will premise that the initial acquisition price is $400.

2). On day 10, the CE pays the wholesaler $400.

3). On day 15, the CE dispenses the drug to a patient that cannot pay the $40 co-pay.

4). On day 15, the CE also submits its claim to the plan.

5). On day 21, the CE submits to the manufacturer for the rebate. This is a conservative parameter, as the data necessary to complete the rebate request is available and is transmitted on day 15 to the plan.

6) On day 31, the CE is paid $200 from the manufacturer. Those funds come to it two weeks faster than it sees any reimbursement from the plan under the discount model scenario.

7.) On day 45, in compliance with a 30-day plan payment mandate, the Part D insurer pays $360.[34]

To assess the interest costs associated with the rebate Pilot, we apply the same 12% CE borrowing cost on a per annum basis.[35] The interest cost is $400 * (31 days – 10 days) * 12% / 365 days, with the addition of $200 * (45 days – 31 days) * 12% / 365 days. That is $3.22 on a $400 list price, a $200 net 340B price, and a $160 "spread" between the acquisition cost and its reimbursement value.

The difference between the discount model and the Pilot is smaller. The additional interest cost of the Pilot is just $0.92. That $0.92 can then be compared to the same $400 list price, a $200 340B net price, and the $160 spread.

Discussion

Covered entities allege in litigation that the rebate Pilot will force them to stop providing patient assistance. Our empirical model does not support that contention. The interest costs associated with the Pilot are only marginally higher than the existing discount model. In the scenario we modeled, the difference in discount and rebate models in a drug dispense involving a full copayment waiver is just $0.92 on a $400 drug or 0.23% of the cost of the drug.

Although we can apply increased copayment obligations and waiver values under our model, the interest cost under the Pilot is marginal in all scenarios. If we apply, for instance, an increased copayment obligation and support amount of $80, doubling the initial values we used, the interest cost impact of the Pilot is now just $0.46. As co-payment waivers increase, the interest cost differences between the discount model and the Pilot actually decline. Indeed, at a cost-sharing waiver of $120, the interest cost of the discount and the Pilot are the same.

HRSA also found that there would be some administrative and operational costs associated with the Pilot. Specifically, it determined that those costs will average $34,320 per covered entity[36] over the more than 15,000 340B covered entities. We considered whether these additional costs could impact 340B charity care and patient assistance, as the litigants in the HRSA lawsuit contend. We do not see a basis to conclude that they would have such an effect, however, for multiple reasons.

---

[33] In the litigation, plaintiffs contend that they may lose these additional discounts under the rebate model, but they provide no evidence that wholesalers have threatened that and no public statement to that effect has been made by any wholesaler.

[34] This is also a conservative parameter, as this assumes that the plan pays an amount considerably less than the list price of the drug.

[35] As our prior research shows, borrowing costs for other covered entities is substantially lower than for clinics, but, consistent with the conservative approach we take here, we apply the higher clinic borrowing cost parameter.

[36] HRSA Rebate Notice, 91 Fed. Reg. at 48,893.

© 2026 Washington Legal Foundation

First, the marginal administrative and operational costs identified by HRSA need not be allocated just to the more than 15,000 covered entities, they must also be allocated across covered entity dispenses[37] Covered entities make millions of dispenses each year for MFP drugs. This underscores the relatively marginal nature of those costs on a per dispense basis

Second, the necessity of cost-sharing assistance in the context of the Pilot is itself quite limited. The Pilot only applies to Medicare Part D patients, all of whom have insurance and many of whom have assistance with cost-sharing obligations under the Low Income Subsidy[38] (LIS) and other programs. Approximately 13.6 million Medicare beneficiaries will receive LIS assistance on their Medicare cost-sharing obligations in 2026.[39] This is only one form of assistance available to a variety of Part D beneficiaries independent of any assistance that might be provided by a 340B covered entity.

Third, Medicare out-of-pocket costs are capped at no more than $2,000, meaning a patient under the Pilot cannot have a drug need in excess of that amount, regardless of the drugs utilized. For many patients, that $2,000 cap will be allocated to Part D drugs that are not subject to MFP in 2027. For all those drugs, the Pilot will not impose any additional costs.

Fourth, HRSA determined that the drugs subject to the Pilot represented just 5.5% of all 340B drugs.[40] Cost-sharing for MFP drugs in 2027 is just a small fraction of that fractional share of 340B drugs.

Finally, the fact that charity care has decreased sharply for many years even as 340B profits have increased many fold shows that charity care commitments are not correlated with 340B spread. The premise of the lawsuit allegations is that lower 340B costs mean higher 340B spreads and, therefore, more charity care and patient assistance. The data shows the opposite. As 340B spread increased by 700% under a predominate discount model, charity care declined by 27 to 40%.[41] Another study examined whether hospitals increase their charity care after they enter the 340B program, and it found they did not.[42] The premise of critics of the Pilot that more 340B profits lead to more charity care and patient assistance is inconsistent with the data.

For all these reasons, we find no evidence that the rebate Pilot should have any material impact on charity care and patient assistance.

Conclusion

After years of consideration, with fraud and abuse concerns increasing, HRSA has adopted a rebate model to bring a measure of transparency to the 340B program. Although the litigants challenging the Pilot argue it will force covered entities to stop providing charity care and patient assistance, that contention is inconsistent with the evidence that most 340B eligible patients receive marginal levels of assistance now and that the Pilot will have a marginal effect on those entities.

---

[37] *Id.*

[38] 42 U.S.C. § 1395w-114.

[39] Kaiser Family Foundation, Medicare Part D Enrollment, Premiums, and Cost Sharing in 2026 (2026).

[40] HRSA Rebate Notice, 91 Fed. Reg. at 48,893.

[41] *See, supra*, at fn. 7.

[42] *See, supra*, at fn. 27.

© 2026 Washington Legal Foundation