

Sales from controversial drug discount program rose to \$66 billion last year

The 340B Drug Discount Program was intended to serve hospitals and clinics serving lower-income patients

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Prescription medicines purchased in the U.S. under a controversial government discount program amounted to \$66.3 billion in 2023, a 23.4% increase from the previous year, according to the Health Resources & Services Administration, which oversees the program.

The data mark a steady rise in sales under the 340B Drug Discount Program, which requires drugmakers to offer discounts that are typically estimated to be 25% to 50% — but could be higher — off all outpatient drugs to hospitals and clinics that primarily serve lower-income patients. There are more than 12,000 entities participating in the program, a number that has grown substantially.

Since it began more than 30 years ago, the program has ballooned and fed into the national clash over the cost of medicines. Some \$38 billion in prescription medications were purchased under the 340B program in 2020, for instance, which was up from \$16.2 billion in 2016. And this fast-paced trajectory has triggered a battle between the pharmaceutical and hospital industries.

Four years ago, many large drugmakers began limiting some discounts when hospitals or clinics bought medicines and then shipped them to contracted retail or specialty pharmacies for patients to pick up or for

delivery, instead of using their own in-house pharmacies. The drug companies alleged that using contract pharmacies led to abuses, such as duplicate billings, product diversions, and ineligible rebates.

However, the move to curtail discounts or restrict the use of contract pharmacies sparked an outcry among lawmakers, state attorneys general, and dozens of patient groups that argued the moves violated federal law. Moreover, pharmaceutical industry critics complained that low-income populations were placed at a disadvantage, especially since the changes began during the Covid-19 pandemic.

More broadly, the clash reflects wider concerns over how 340B funds are being used. A [recent study](#) in JAMA found that 340B subsidies translated into increased access to unprofitable services at some, but not all, hospitals serving disproportionate numbers of patients who require safety net services. The authors suggested increased regulatory oversight and program transparency is needed.

“The data spotlight the increasing gulf between the growth of the 340B and the lack of any evidence that patients are benefiting from those discounts,” said Brian Reid of Reid Strategic, a consultant who specializes in pharmaceutical pricing issues. “There’s been a lot of research that has tried and failed to show an association between charity care spending and the growth of 340B. That raises questions about where 340B related revenue is going, if not to that kind of patient care.”

“What troubles me is not the expansion itself, but the lack of evidence that patient assistance at the pharmacy counter or charity care more broadly is expanding at a comparable rate,” said William Sarraille, professor of practice at the University of Maryland Francis King Carey School of Law.

We asked the American Hospital Association and 340B Health, two trade groups that represent hospitals that participate in the program, for comment and will update you accordingly.

However, in a [report](#) issued earlier this year, the AHA argued that “estimated increases in the amount of 340B hospitals’ community benefits have outpaced the growth in 340B discounts, consistent with the Congressional intent of the program. This outsized impact with direct

benefits to patients comes at no additional cost to taxpayers and accounts for a small share of drug company revenues.”

The controversy has sparked a spate of litigation between several pharmaceutical companies and the federal government over the regulations governing the use of contract pharmacies. At the same time, several states and drug companies have also gone to court over laws that were passed to curtail restrictions on these pharmacies.

For instance, a pharmaceutical industry trade group filed a lawsuit arguing an Arkansas law, which was adopted three years ago, is unconstitutional, because it is preempted by federal law and also violated the Commerce Clause of the U.S. Constitution. This clause restricts state governments from interfering with interstate commerce.

The lawsuit was seen as a litmus test for industry arguments that states should not be permitted to restrain drugmakers from imposing restrictions on how medicines are distributed by hospitals under the program. A U.S. appeals court, though, upheld the law. But then AstraZeneca filed a lawsuit that made slightly different arguments. AstraZeneca and AbbVie are also challenging a Louisiana law, and Novartis filed a lawsuit against Maryland officials over a state law.

Separately, various drugmakers have filed still other lawsuits against the Department of Human and Health Services, which oversees the HRSA, over a 2021 advisory opinion that maintained pharmaceutical companies should provide discounts, even if hospitals and clinics use contract pharmacies to deliver drugs. The agency noted that, as a practical matter, some hospitals and clinics are forced to rely on contract pharmacies for distribution if patients live far away.

The lawsuits have argued that HHS skirted usual procedures and maintained HRSA should have first provided notice before an opinion was issued. The companies also insisted the program does not require them to provide discounts to multiple contract pharmacies. The clash intensified after the HRSA told each drug company to immediately offer medicines to hospitals and clinics that rely on contracted pharmacies, and later began referring some of the companies for potential penalties.

Meanwhile, U.S. federal court judges overseeing these separate lawsuits have issued varying rulings on the HHS opinion and the agency's authority to require the drug companies to reinstate discounts. In the latest decision, a federal appeals court recently ruled that drugmakers can limit sales of discounted drugs under the 340B program.

Other companies have pushed back in different ways. Johnson & Johnson recently planned to issue rebates to some hospitals for two widely prescribed medicines instead of offering discounted prices, arguing the program was not meeting its original goal of allowing so-called safety net providers to obtain discounted medicines for "vulnerable" patients.

But J&J backed down after the HRSA threatened the health care giant with sanctions if it proceeded. The HRSA maintained the proposal violated federal law governing the program because the rebates would be mandatory and force hospitals to pay higher prices up front, not just for initial purchases that are later replenished at the lower 340B pricing.

However, we should note some industry watchers had suggested J&J had another motive. Both Xarelto and Stelara were recently selected by Medicare for price negotiations. And the agency wants manufacturers to ensure the 340B discount and maximum fair price under the Inflation Reduction Act are not applied to the same drug. By offering rebates instead of discounts, J&J may be trying to avoid this conundrum. The company appeared to confirm this issue in its letter to HRSA