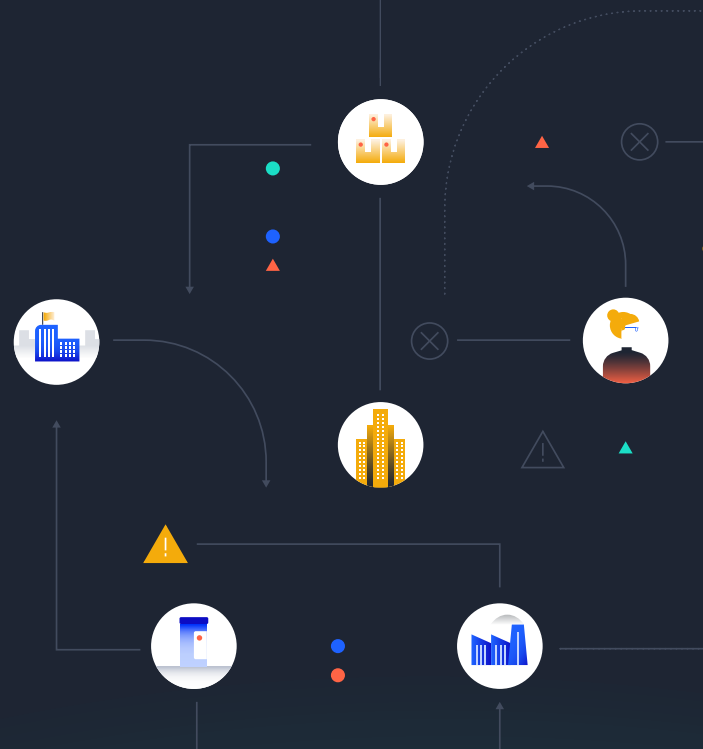


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Following the Dollars: Why 340B Reform Is a Data-Driven Necessity

WHITEPAPER





01

Introduction

The 340B Drug Pricing Program is a financial lifeline for many healthcare providers and the patients they serve. Over 14,000 covered entities (CEs) and over 800 major manufacturers participate in this vital initiative. Since its inception in the mid-1990s, 340B has expanded to cover every congressional district in the country, serving as a critical safety-net mechanism for over [25 million people](#) receiving care from providers who service disadvantaged communities. In 2023, over \$66B of drugs were purchased using 340B discounts, up more than 26x since 2005.

As the program has grown, the increasing complexity of the drug pricing ecosystem has made maintaining compliance onerous for all parties, raising critical questions about both the integrity and sustainability of the program. Regulatory agencies and legislative bodies have done very little to adapt to the changing times and technology as it relates to 340B. As the country grapples with the affordability of prescription drugs, new ways of working together are needed for 340B to function fairly and appropriately for clinicians providing healthcare services to underserved populations, patients in need of life-saving therapies, and manufacturers who are funding the program.

¹ Independent research conducted on behalf of Kalderos.



WHAT IS 340B?

The 340B Drug Pricing Program is a federal program established by the U.S. government in 1992, which requires drug manufacturers participating in Medicaid to provide covered outpatient drugs to eligible healthcare providers, known as covered entities, at significantly reduced prices. The decreases in drug costs allow covered entities to stretch scarce federal resources to reach more eligible patients and provide more comprehensive services.



340B is allowing us to keep a hospital that's been operating at a loss for over a decade open because it allows some cost savings and revenue across the system, which can then support those under-performing facilities and keep vital services open.

– COVERED ENTITY REPRESENTATIVE
FROM MID-TIER HOSPITAL ¹



02

Meaningful Reform, Meaningful Impact

We sat down with covered entities, policymakers, and manufacturers to hear about their challenges and concerns with 340B. Despite the fact that most agree that the program has had a meaningful impact on underserved patients, here's what they wanted us to know¹:

- Healthcare executives worry that 340B savings are not being passed on to patients as intended due to waste and inefficiencies in the sector.
- Compliance with the program is onerous, leaving some covered entities to rely on third-party administrators and consulting firms to stay in compliance with the program's requirements (e.g., proving they qualify and identifying duplicate discounts). This means that some portion of the dollars intended to subsidize care for underserved populations ends up being diverted to these intermediaries as opposed to using the manufacturer discounts for their intended purpose.
- Many called out a lack of accountability and oversight from all sides, leading to negative consequences for those who need the program most.
- Manufacturers are struggling to ensure program integrity without quality data to properly manage it.

340B helps providers get patients the treatment they need, but reform is needed to ensure all parties have visibility into the data they need to be compliant and get the most out of the program.



74%

of healthcare executives surveyed believe 340B needs to be reformed

¹ Independent research conducted on behalf of Kalderos.

Common misunderstandings about the 340B program

COMMON MISUNDERSTANDING #1

Taxpayers or the Health Resources and Services Administration (HRSA) cover the costs of 340B discounts.

TRUTH

The burden of covering 340B discounts falls exclusively on manufacturers.

COMMON MISUNDERSTANDING #2

Through 340B, patients receive discounted medications at pharmacy counters.

TRUTH

340B discounts directly benefit the covered entities providing care. While some report passing on these savings to patients, most do not.

COMMON MISUNDERSTANDING #3

Problems with 340B are caused by a few "bad actors" who take advantage of the program.

TRUTH

While bad actors make headlines, most non-compliance seems to be unintentional. The lack of transparent data makes it challenging to catch issues early before they grow, and without a central data ledger, participants are often unable to see the full picture.

¹ Independent research conducted on behalf of Kalderos.



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Managing Multiple Drug Pricing Programs with Compliance and Transparency

Often, 340B reform efforts are limited to the administrative nuances of the program, focusing on ensuring that discounts are compliant. But there's more to it. The intersection of 340B with other government programs creates an added layer of complexity that leads to inefficiency, higher administrative costs, waste, and the potential for fraud and abuse.

The reality is that healthcare providers and manufacturers aren't only managing discounts through 340B. They also must ensure compliance with the Medicaid Drug Rebate Program (MDRP), commercial drug discount plan contracts, and soon, the Inflation Reduction Act, which will impose a Maximum Fair Price (MFP) on medicines paid for by Medicare. Each program brings unique challenges, and while some respond to the evolving healthcare ecosystem, the 340B program has remained relatively untouched, creating disconnects within the broader healthcare environment.

The complexity caused by the intersections of these programs presents management challenges as the 340B program is not aligned with the other guidelines. Whereas most discounts are provided at the unit-level, based on what is dispensed to an eligible patient, the 340B program applies discounts at the time the inventory is acquired with only a "handshake promise" that the discounted drug will be dispensed to an eligible patient.

Overview of government drug pricing programs

340B: The 340B Drug Pricing Program is a government initiative that requires drug manufacturers to deliver covered outpatient drugs to eligible providers at significantly reduced prices to stretch scarce federal resources, reach more patients, and provide more comprehensive services.

Medicaid Drug Rebate Program: The Medicaid Drug Rebate Program (MDRP) requires drug manufacturers to pay quarterly rebates to states for covered outpatient drugs administered to Medicaid patients. These rebates are shared between the states and the federal government to offset the overall cost of the Medicaid program.

Max Fair Price: Max Fair Price (MFP) is part of the 2022 Inflation Reduction Act (IRA), which was passed to address escalating drug costs in the U.S. Under the IRA, the Centers for Medicare and Medicaid Services (CMS) negotiates reimbursement rates with manufacturers of certain high-cost, single-source drugs, setting a maximum fair price. When negotiated drugs are dispensed to Medicare Part D beneficiaries, dispensing entities will be paid the MFP for the drug's cost by CMS, and manufacturers will be responsible for paying the difference between the MFP and the acquisition cost of the drug. MFPs for the first 10 negotiated drugs will go into effect on January 1, 2026.



04

Addressing Drug Pricing Challenges

Contract pharmacy policies aimed at expanding access to discounted medications fall short

With the current challenges of managing the various drug pricing programs, what is the best way forward to minimize complexity, standardize processes, and increase transparency? Some manufacturers have established policies addressing 340B use by covered entities through contract pharmacy arrangements. Covered entities, especially those in rural communities and without in-house pharmacies, partner with either external retail or specialty pharmacies to dispense medications to patients at affordable prices. However, contract pharmacy policies require additional paperwork and data maintenance, carrying restrictions on how many contract pharmacies a covered entity can partner with, and adding to the complexity of today's drug pricing program. The efforts required to monitor and pursue corrective actions for compliance issues arising in these relationships are highly burdensome.

While these contract pharmacy policies initially resulted in lower noncompliance, many covered entities developed workarounds, such as obtaining dispensing records from one pharmacy and then using those dispenses to justify 340B purchases on another (possibly unrelated) account. The covered entity would then receive the inventory at one location, and if necessary, transfer the inventory to another location. The specific operations of alternative distribution models vary greatly due to independent state laws around corporate structuring and distributor registration requirements, which only add layers of complexity, increase potential for noncompliance, and obfuscate the process. Interestingly, despite new contract pharmacy policies aimed at addressing compliance issues, 340B sales continued to grow 15.9% year-on-year in 2021.² Current approaches aren't solving the underlying compliance challenges—and the growth they were meant to curb continues to accelerate.

² "340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect", Rory Martin, PhD, IQVIA Market Access, IQVIA



A rebate model is the best path forward

Truly addressing 340B noncompliance requires resolving the problem at the source. While improving drug pricing management within the current model is possible, our research has found that a rebate model is the best way forward to achieve a fully compliant and transparent drug pricing ecosystem that ensures the correct discount is applied quickly and without duplication. With a rebate model, the covered entity dispenses a drug to a patient after purchasing it at a non-340B price point. After verifying the patient is 340B eligible, the covered entity submits a claim for a rebate. The manufacturer reviews the claim-level detail elements, confirms the eligible discount request, and directs payment to be made to the covered entity via secure account-to-account bank transfers.



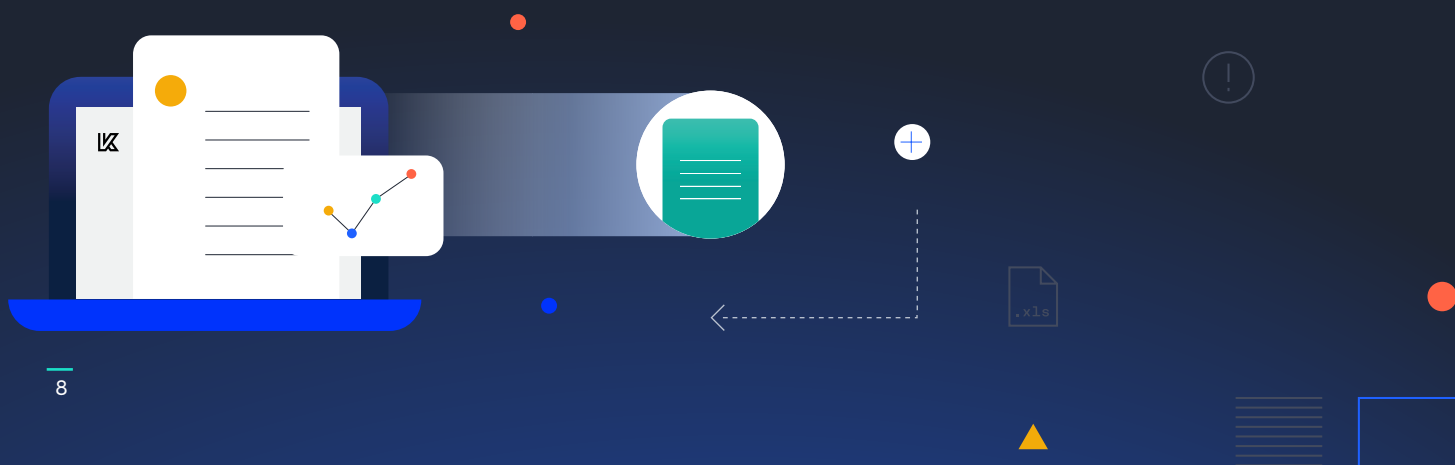
² "340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect", Rory Martin, PhD, IQVIA Market Access, IQVIA

The Rebate Model:

- A rebate model ensures no duplication of a discount can occur, since each payment is linked directly to a single claim and logged in a single ledger.
- Rebates are based on itemized data up front, instead of blindly accepting 340B inventory will be dispensed to eligible recipients.
- Covered entities no longer must wait until a full package quantity is needed before requesting and receiving 340B pricing – they get a rebate for every unit dispensed or administered.
- The rebate model uses data that covered entities are already collecting and using to justify purchases.
- Data is harmonized and creates a ledger with high-quality, clean inputs that lead to usable insights.
- Streamlining and standardizing the data will result in fewer full-time equivalent (FTE) hours spent reconciling disparate purchasing, dispensing, and billing data for auditing.

Product Replenishment Model:

- In a product replenishment model, covered entities must purchase replacement units when an eligible drug is dispensed through a chargeback process, often taking weeks or months.
- This current model does not provide the claims-level data needed to ensure compliance and give clarity, which enables program abuse.
- Covered entities determine 340B eligibility after the fact and can lose sight of the data that manufacturers need, creating data silos and disparate data systems that muddy the waters.
- With a replenishment model, it is difficult for manufacturers to determine if a Medicaid rebate is being paid on 340B units or not.





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How Truzo Works

Managing the intersection of drug pricing programs requires quality data and transparency between parties. Truzo enables a new way for pharmaceutical manufacturers, providers, and payers to come together, share data, and manage drug discounts across multiple programs.

A model-agnostic, end-to-end solution, Truzo is not limited to just 340B, giving manufacturers and covered entities the ability to manage all drug pricing holistically from one platform.

SUPPORTING A VIABLE AND SUSTAINABLE DRUG DISCOUNT ECOSYSTEM

Truzo manages the intersection of all drug pricing programs and ensures their sustainable growth through the transparent sharing of quality data.

- Manage overlap with MDRP and commercial programs.
- Detect duplication across MDRP, 340B, commercial, and MFP, plus within each individual program.
- Resolve discount disputes via our dedicated covered entities support team.
- Plan for the future with a purpose-built IRA MFP solution and manage the overlap of MFP with other programs.
- Effectuate MFP & 340B discount payments if desired.
- Monitor for hotspots where duplication or diversion may be occurring.
- Manage contract pharmacy restrictions and collect claims data directly from the covered entity.
- Adapt to regulatory or program changes seamlessly.

PAVING THE WAY TO A REBATE MODEL

As of mid-2025, the 340B regulatory landscape is in flux, but manufacturers and covered entities can still take steps to put themselves on a path to a rebate model. The rebate model is steadily gaining momentum and is widely seen as the inevitable progression toward enhancing transparency and integrity within the program, as demonstrated by HRSA's 340B Rebate Model Pilot Program. As previously discussed, high-quality claims data sits at the center of it all to ensure discount integrity regardless of the model. With that in mind, manufacturers can get started by:

- Collecting all 340B dispense and administration data from every covered entity for all retail, acute, and outpatient care areas to create a central data ledger to rationalize and standardize data across programs.
- Implementing a process for resolving good-faith inquiries at scale.
- Incorporating sales and utilization analytics to highlight anomalies and prompt further investigations.
- Ensuring cross-program duplication detection is scalable and adaptable in the event programs get added or change.

You don't need to go all-in at once. Starting to collect data from covered entities now will make it easier to implement a rebate model in the future and unlock more value than ineffective contract pharmacy restrictions.

TRUZO BRINGS TRANSPARENCY AND TRUST TO DRUG PRICING

TruZO creates a single source of truth by establishing a direct connection between manufacturers and providers and gives access to complete claims-level data. This helps manufacturers identify and resolve non-compliant discounts and builds trust between all parties. TruZO ensures every eligible claim is paid and prevents duplicate discounts in real time. This not only benefits both sides but also ensures integrity in drug pricing programs that will have long-term positive impacts on the patients and providers they serve.





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Fostering a Sustainable Drug Discount Ecosystem for All

The future of 340B—and other vital drug pricing programs—depends on a system built on trust, transparency, and accountability. Both manufacturers and covered entities have a shared stake in protecting these lifelines and a responsibility to participate with integrity. That's why we created Truzo, a purpose-built solution to manage the complexity of drug discount compliance and support a viable and sustainable drug discount ecosystem. Because without better visibility and collaboration, the system risks breaking down—hurting the very patients it was meant to serve.

Truzo is the flexible solution for your existing programs and for the models and programs of the future, bringing care team stakeholders together to manage drug pricing programs with confidence and clarity so that patients can access the affordable medications they need.

Learn more about how Truzo can help ensure transparency and accountability in your drug pricing programs.

gotruzo.com

About Kalderos: Kalderos is a healthcare technology company building the industry's only truly independent platform for drug pricing transparency and integrity. Our platform, Truzo, enables manufacturers, providers, payers, and government entities to collaborate with confidence by delivering shared visibility, verified insights, and fully compliant pricing reconciliation that benefits the entire healthcare system. By combining advanced data infrastructure, machine learning, and a stakeholder-neutral approach, Kalderos is creating a brighter, fairer, and more efficient system for pricing and paying for drugs. Founded in 2016 and headquartered in Chicago, Kalderos is working to eliminate waste, strengthen trust, and unlock better outcomes across the healthcare system.

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