

Kalderos | OMB

340B Rebate Guidance Input

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Recommendations for HHS

- HHS/HRSA should issue guidance to establish a standardized “Claims-based Rebate Model” that includes federal guardrails to ensure consistency, transparency and efficiency
- Guidance is needed so that covered entities can be sure they are interacting with reputable platforms and in a consistent manner that reduces burden
- Guidance for an approvable Model should include the following standards:
 - Standard data fields from claims,
 - Security protocols for protecting potential PHI and other sensitive data,
 - Security systems to protect against cyber-attacks
 - Timelines for reviewing claims data and transactions
 - Transparency that allows both covered entities and manufacturers to see the same data at the same time as well as the ability to share the data with HHS
 - Penalties for manufacturers & providers who don’t comply with the standards

Definitions

Rebate	“Rebate” is a triggering word; we are using it in this presentation because it is the language in the statute. The Kalderos model provides CE’s with the 340B price, effectuated via cash replenishment directly from the manufacturer to their CE bank account within 7 days of a unit dispense.
Cash Replenishment	Today’s model for 340B is a product replenishment model, meaning CE’s purchase at WAC and receive the 340B price via product replenished, once the entire package has been accumulated, at the discounted price. The Kalderos model changes this paradigm from product to cash replenishment and from accumulation to unit.
Truzo	This is the brand name for the Kalderos’ products. The brand name was selected to represent transparency, trust and truth.



340B Program Challenges

- 340B lacks transparency, oversight and has strayed from its original purpose.
- The complexity of the program has rapidly grown and attempts to bandaid operations, have failed and will continue to fail without significant change.
- Implementation of a rebate model for 340B is necessary to ensure sustainability and integrity of the program for providers (covered entities), manufacturers and regulators.
- PBM's and other middlemen are financially benefiting from the opacity of the existing system. The Truzo rebate model represents a middle ground between key stakeholders (manufacturers and covered entities).
- The existing audit process is exceptionally difficult and HRSA initiated audits are capped at 200 per year. The Truzo model will facilitate the dispute resolution process by maintaining a canonical audit for every rebate claim request.

Accelerating Growth & Complexity

Growth in Program Complexity

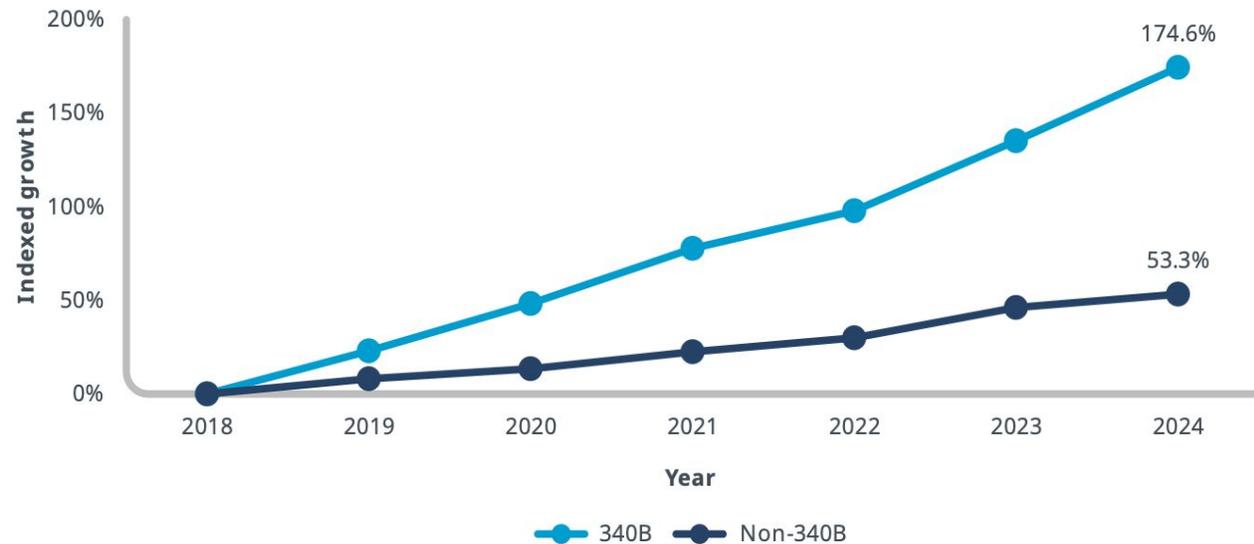


Growth of Drug Discounts

175%

Cumulative Growth Since 2018

Figure 2. Cumulative year-over-year growth for 340B purchases and non-340B purchases at list price, indexed to 2018

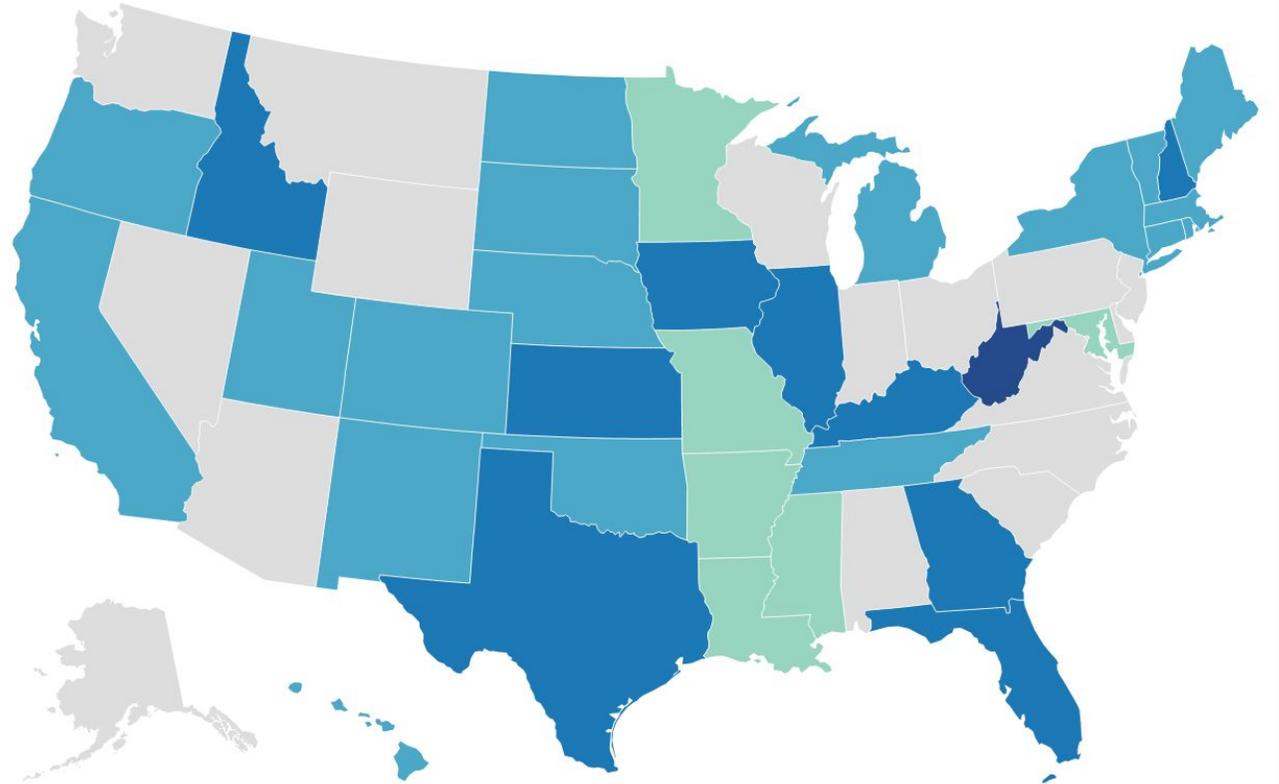


Source: IQVIA, The Size and Growth of the 340B Program (May, 2025)

Interstate Complexity

- Lack of federal regulations have induced states to enact specific policies
- The policies are non-standardized and often require customized approaches
- For example:
 - 18 states with contract pharmacy policies
 - 12 with specific limitations re: claims-level data access

State Contract Pharmacy Activity



Created with Datawrapper

Massive Scale

Breaking down
huge numbers...

\$148B

In 340B sales

\$80B

In 340B discounts



\$405M

Sales per day

\$219M

Discounts per day

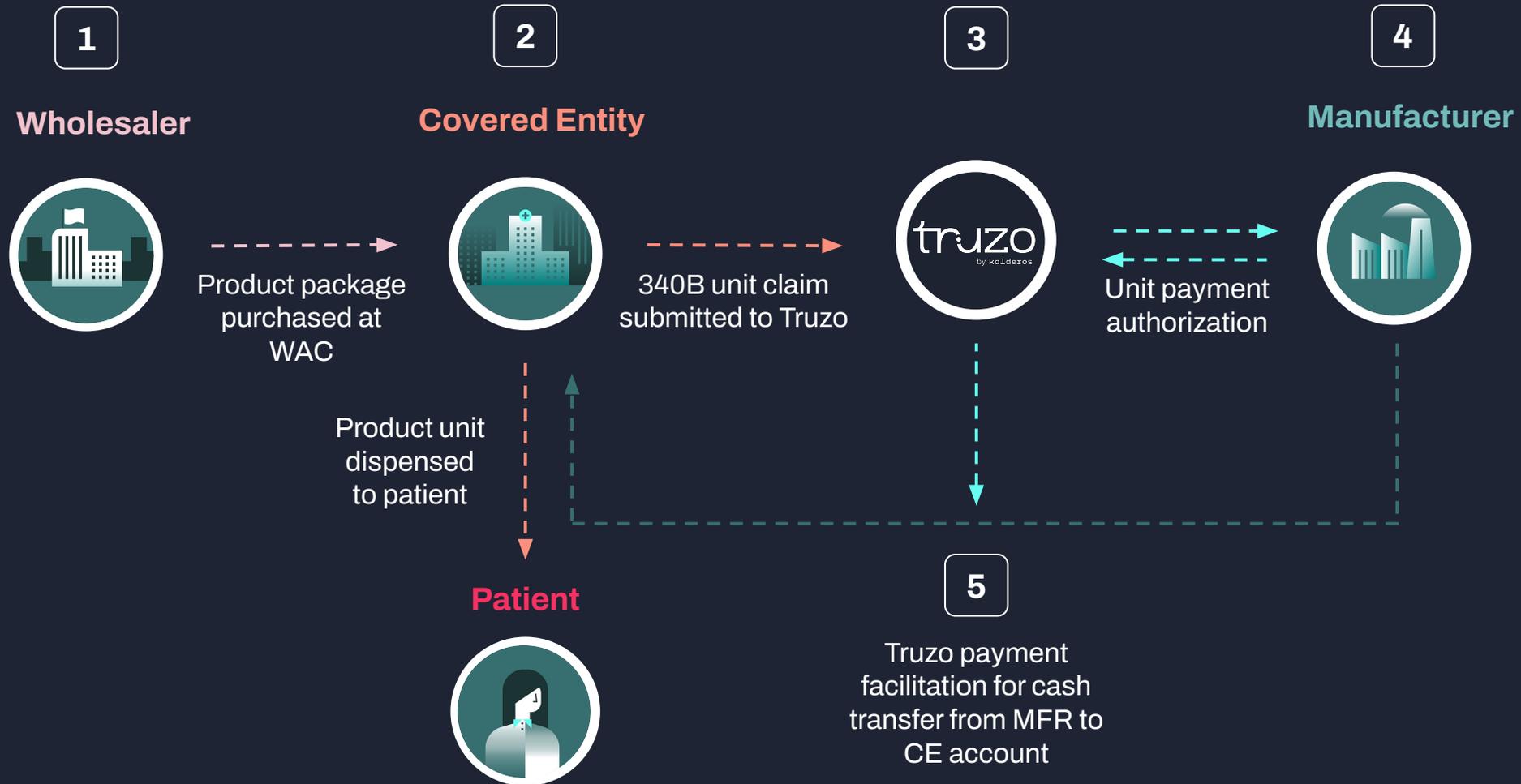
\$17M

Per hour

\$9M

Per hour

Truzo Rebate Model Flow



Rebate Model Benefits All Stakeholders

- 1 Cash rebates price paid **directly** vs. getting product replenished retrospectively
- 2 **Claims data** is submitted for payment, instead of probabilistic matching chargebacks. Providing all stakeholders access to the same transparent data.
- 3 Discounts are paid **per-unit**, vs waiting for package-based accumulation
- 4 **Secure & automated** data exchange supported by fully staffed CE resource team
- 5 **Canonical transactional ledger** to support any audit, CE or regulatory inquiry

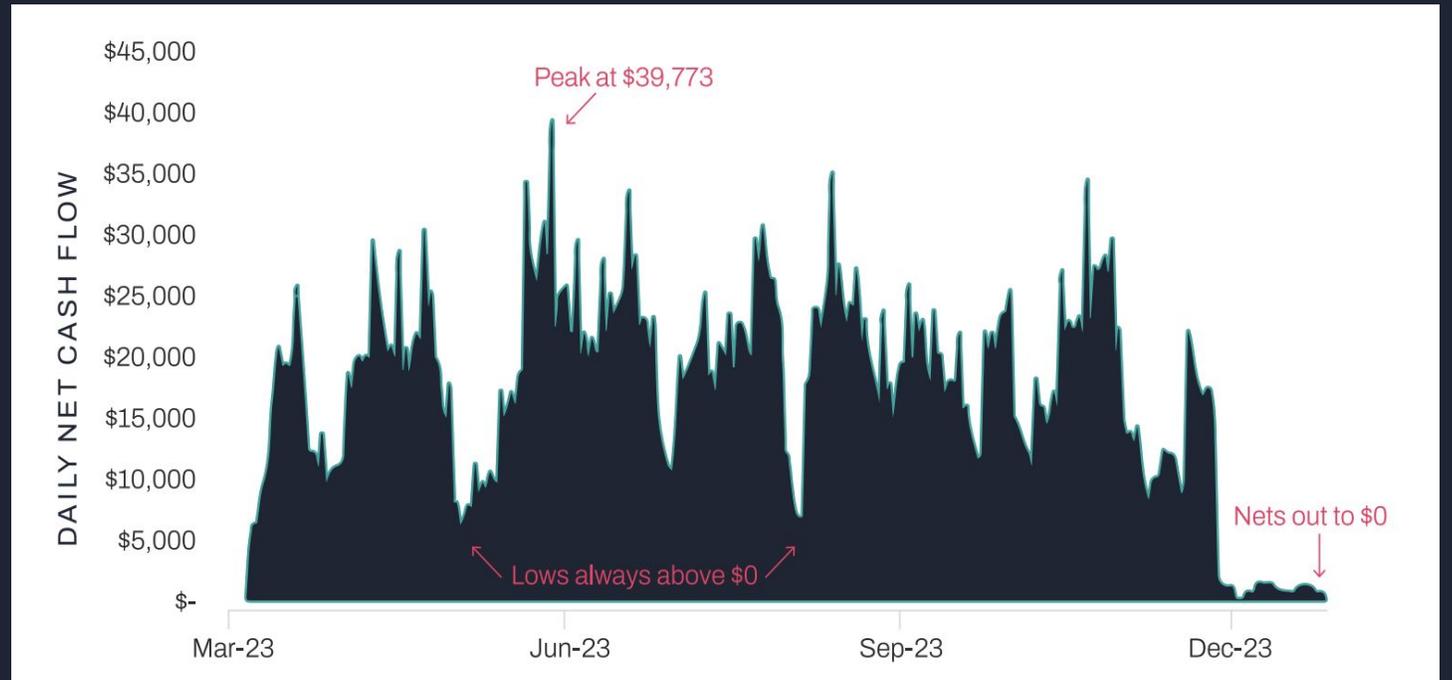
Compliance with Existing and Future Obligations

LEGAL OBLIGATION	ISSUE	REBATE MODEL SOLUTION
<p>Medicaid:340B Duplicate Discount Prohibition</p>	<p>Lack of transparent data prevents accurate identification of duplicate discounts and increases participant resources to investigate and resolve</p>	<p>Rebate model allows direct claim matching (not probabilistic or algorithmic matching).</p>
<p>MFP:340B Duplicate Discount Prohibition</p>	<p>CMS has placed responsibility on manufacturers to pay MFP within 14 days, but has not provided any guidance on de-duplication.</p>	<p>Enables manufacturers to match claims and adjust pricing based upon MFP/340B comparison.</p>
<p>340B ADR Obligations</p>	<p>Regs require manufacturers to provide data that they do not own or control.</p>	<p>CE and manufacturer have access to the same data to be used for ADR process.</p>

Positive Cash Flow Impacts on Covered Entities

An analysis of an anonymized covered entity shows their daily cash flow improvements over the course of a year under the Direct Discount Model.

- Average surplus of \$16,718 per day
- Lows always well above \$0 and remain positive throughout the year
- Nets out to neutral by the end



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Discussion