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Navigating 340B and Rebates

Challenges, Solutions, and the Path Forward

Amy Martin, PharmD, BCPS | *VP, Access Experience Team*
Angelica Norrell, PharmD, BCOP, CSP | *Sr. Director, Access Experience Team*

Introduction

Established in 1992, the 340B Drug Pricing Program was designed to help safety-net providers stretch scarce resources by allowing the purchase of drugs at significantly reduced prices. The resulting savings were intended to support care for underserved populations. However, as the program grew to reach more than $33 billion annually, it became a point of contention among pharmaceutical manufacturers, healthcare providers, and policymakers.

A Key Challenge: Duplicate Discounts and Lack of Transparency

At the heart of the controversy is the concern over duplicate discounts. Under Medicaid, statutory protections shield manufacturers from having to provide both a 340B discount and a rebate on the same drug. However, no such statutory protection exists under Medicare or commercial insurance and rebate contract language may also offer limited protection.

Manufacturers may unintentionally provide a 340B discount to a covered entity and also pay a rebate for the same drug if the duplicate claim is not identified. It is particularly problematic when the contracted pharmacy is vertically integrated with the payer and data firewalls prevent visibility into 340B eligibility. IQVIA estimates that $34B to $37.5B of sales at wholesale acquisition cost (WAC) pricing may be at risk for rebate/340B duplicate discounts.

Proposed Solutions: Pros and Pitfalls

Several solutions have been suggested to address the duplicate discounts, each with their own set of trade-offs as outlined below.

1. Aligning Chargeback and Rebate Systems

Merging the chargeback system used in 340B with the rebate system used by payers may theoretically streamline processes, but may also significantly disrupt cash flow for payers and contract pharmacies. Payers may experience a drastic reduction in rebates and contract pharmacies might face reduced dispensing fees. Moreover, this approach lacks congressional support, making it politically unviable.

2. Post-Sale 340B Rebate Models

Several manufacturers have proposed 340B rebate models for some of their products. These models would require covered entities to purchase drugs at full price and then submit claims data to manufacturers for post-sale rebates, with an aim to preserve covered entity cash flow. Limitations of this type of model include the complex adjudication process needed to determine 340B eligibility post-sale, a perceived lack of support from stakeholders, and delayed 340B discount payments, making this solution less attractive. In fact, the rebate model has faced strong resistance from covered entities and legal scrutiny. In May 2025, a federal court ruled that manufacturers cannot unilaterally impose rebate models without approval from the Health Resources and Services Administration (HRSA). While the ruling upheld HRSA's regulatory authority, it left the door open for future negotiations.

HRSA announced the availability of a voluntary 340B Rebate Model Pilot Program initiative for drugs on the CMS Medicare Drug Price Negotiation Selected Drug List for year 2026 on July 31, 2025. Its purpose is to evaluate the feasibility of such a program, address concerns about 340B structure, and promote transparency of the 340B model. A 30-day public comment period will end August 30th.

3. Leveraging the Medicare MTF Platform

A promising approach may lie in using the Medicare Transaction Facilitator (MTF) platform to process 340B claims. The proposed 2026 U.S. Department of Health and Human Services (HHS) budget suggests that the 340B program could shift from HRSA to the Centers for Medicare & Medicaid Services (CMS), which would oversee eligibility, audits, and data systems. Requiring 340B claims to flow through the MTF platform could enhance transparency, eliminate duplicate discounts, and create a unified data-sharing environment between manufacturers and dispensing entities.

Looking Ahead: A Call for Reform

There is a broad consensus that the 340B program needs reform, but little agreement on the best path forward. Among the proposed solutions, integrating 340B claims into the CMS MTF platform appears to offer the most balanced approach. It provides a centralized system for data sharing, enhances visibility, and reduces the risk of duplicate discounts—benefiting manufacturers while preserving some level of operational continuity for covered entities.

However, any reform must carefully consider the financial implications for all stakeholders, including covered entities, pharmacy benefit managers (PBMs), payers, and manufacturers. As the healthcare landscape continues to evolve, thoughtful, data-driven policy design will be essential to ensure that the 340B program remains a vital tool for expanding access to care.

Three things manufacturers can do to mitigate their risk for duplicate 340B and rebate discounts include:

1. Update rebate contracts to describe what constitutes a 340B claim.

- For example, including terms that a claim is assumed to be 340B if it's written from a covered entity. This places responsibility on the rebate aggregator to identify and dispute any claims from a covered entity that are not 340B. It also adds pressure to the contracted pharmacy to accurately submit claims with a National Council for Prescription Drug Programs (NCPDP) 340B indicator
- Use claims analysis and artificial intelligence (AI) to identify potential 340B impact so contract terms can be negotiated on how many claims are expected to be 340B from a given covered entity or submitted from a contract pharmacy
- Include contract language that allows for claw back for claims submitted from a covered entity that exceed a predetermined threshold. For example, if the manufacturer analysis indicates a covered entity has 80% 340B but the NCPDP 340B indicator is only used on 15% of claims, the manufacturer may be able to limit rebate payments to only 20% of claims unless the payer demonstrates the claims from the covered entity are not 340B eligible

2. Implement timely rebate audits to identify potential 340B and duplicate payments so that overpayments can be reconciled and data can be tracked on accuracy of submissions.

- Include language on accuracy of non-340B claims within the contract that allows for penalties if 340B claims are not submitted for invoice but are identified as 340B within audit

3. Work with government officials responsible for 340B, policy makers, and payers to support a requirement that pharmacies use the MTF platform to ensure all 340B claims are accurately identified at the time of dispensing across all lines of business.

As the 340B program continues to face scrutiny and calls for reform, manufacturers must navigate a complex and shifting landscape. Addressing risks like duplicate discounts requires a combination of strategic contracting, data transparency, and regulatory awareness.

Learn how Precision AQ's Value & Access Solutions can help you manage these challenges and drive smarter access strategies.

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