Understanding Medicaid and 340B duplicate discounts: Avoiding the “double dip”

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EBOOK

CONTENTS

Duplicate discounts explained 3

Challenges for manufacturers 6

Identifying and avoiding duplicate discounts 9

How Model N can help 11

The 340B Drug Pricing Program and Medicaid Drug Rebate Program are crucial initiatives designed to help healthcare providers serving vulnerable populations provide medications at a discounted price. These discounts include reduced sales prices for 340B-eligible hospitals and federal grantees and rebates shared by state and federal governments for drugs dispensed to Medicaid beneficiaries.

However, rapid growth of the 340B program and lack of transparency and oversight of both programs have created major challenges. One in particular – duplicate discounts – poses a significant risk for pharmaceutical manufacturers.

This eBook provides an overview of the issue and its impact on the industry and outlines data-driven strategies manufacturers can implement to identify and prevent duplicate discounts.

Duplicate discounts explained

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Duplicate discounts explained

Duplicate discounts occur when a drug manufacturer is asked to provide both a 340B discount and a Medicaid rebate for the same drug. This situation is prohibited under 340B program regulations because it unfairly burdens manufacturers and undermines the program's integrity.[1] Double dipping still occurs, however, largely because when manufacturers pay Medicaid rebates, they lack the ability to determine which units in the rebate invoice may have been already purchased at the 340B discount.

Nonetheless, manufacturers often carry the biggest burden of trying to validate rebate claims data and detailed data on 340B drug purchases, especially when they pertain to commercial insurances.

For example, say a covered entity (CE) purchases a $100 drug for $50 (or a 50% 340B discount). The drug is then dispensed by a contract pharmacy (CP) to a patient who has commercial insurance. The third-party payer receives a claim in which it reimburses $105; through a contract with this payer, the manufacturer has agreed to pay a rebate. The CE made $55 on the transaction. Ultimately, the manufacturer paid multiple discounts on the same product: a 50% upfront discount for the 340B price and then another rebate to the insurer. This form of revenue leakage becomes even more pronounced if the 340B discount was "penny priced" – as the manufacturer could end up paying more in discounts than the price of the product.

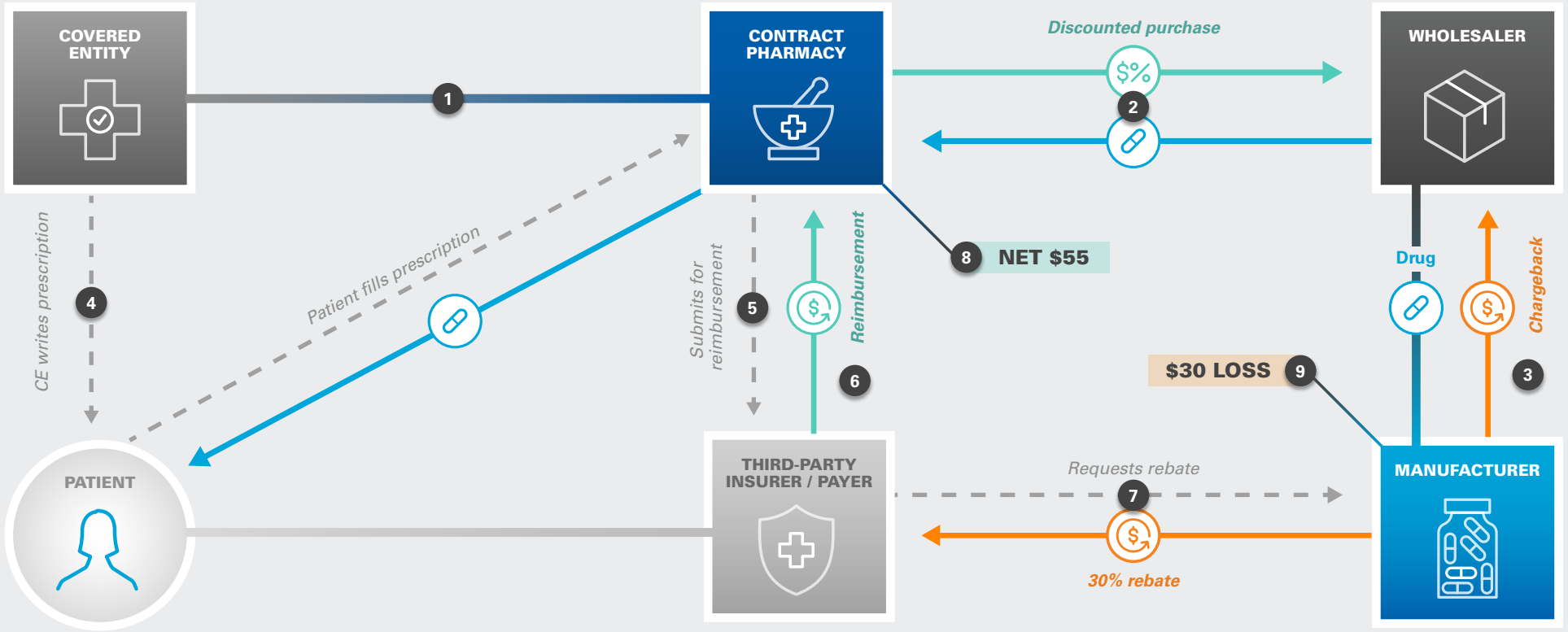
$37.5B

IQVIA estimates that up to $37.5 billion in wholesale acquisition cost (WAC) pricing maybe at risk for duplicate discounts.

[1] 42 USC 256b(a)(5)(A)(i), as described on HRSA.gov, Duplicate Discount Prohibition

Figure 1

What causes a duplicate discount?



1. CE participates in 340B program and engages with a CP.
2. CP purchases drug from a wholesaler at the 340B price of $50 (a 50% discount off the $100 list price).
3. Manufacturer pays a chargeback to the wholesaler for the difference of $50.
4. A patient gets a prescription from a doctor at a CE. The patient fills the prescription at the CP, showing their card for third-party insurance.
5. The CP submits the prescription to the third-party payer for reimbursement.
6. The payer, which has contracted with the manufacturer to receive a rebate, reimburses the pharmacy $105.
7. The payer requests and receives a 30% rebate from the manufacturer.
8. The CP made $55 on the transaction.
9. The manufacturer paid multiple discounts on the same product – 50% upfront discount for the 340B price and 30% rebate to the insurer – resulting in $30 of revenue leakage.

Challenges for manufacturers

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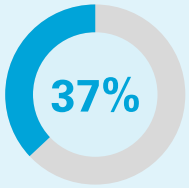
Challenges for manufacturers

Many manufacturers lack the human and technological resources to accurately track the massive number of transactions occurring amid 340B's explosive and largely unchecked growth.

Originally introduced as a section within the Veterans Health Care Act of 1992, the 340B program has grown to become the second-largest drug program in the U.S. – right behind Medicaid. In 2023, CEs purchased $66.3 billion in covered outpatient drugs under the 340B program.[2] The latest available data indicates as many as 50,000 CEs participate in 340B,[3] including disproportionate share hospitals, children's hospitals, freestanding cancer hospitals, federally qualified health centers, rural referral centers, and many others. Many of these CEs contract with outside pharmacies to help facilitate distribution of eligible outpatient drugs under the program. By recent count there are approximately 33,000 of these CPs,[4] each of which may contract with multiple CEs.

Lack of oversight and data transparency into these relationships make it extremely difficult for manufacturers to link CE purchases to actual drug dispensing, contributing to the risk of these costly duplicate discounts.



of corporate leaders are paying close attention to the expansion of 340B, according to the 2025 Model N State of Revenue Report.

[2] Health Resources & Services Administration. "2023 340B Covered Entity Purchases."

[3] USC Schaeffer. "The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments." October 14, 2021.

[4] Drug Channels. "Hospitals Are Relying More on PBMs to Manage Manufacturers' 340B Contract Pharmacy Restrictions: DCI's 2024 Market Analysis." June 12, 2024.

Cost impact

To provide an estimate of the problem, consider the following industry metrics regarding both Public Health Service (PHS) sales and Medicaid prescription utilization:

- In 2023, U.S. pharmaceutical gross sales totaled approximately $678 billion.[5]
- The gross equivalent of PHS sales is difficult to assess, but can be estimated:
  - Health Resources and Services Administration (HRSA) reported discounted PHS sales in 2023 at $66 billion.[6]
  - The PHS price is based on the Medicaid discount; therefore, using the statutory minimum Medicaid discount of 23.1%, the equivalent gross sales value would be about $86 billion. Rounding up, estimated PHS sales represent at least 13% of all U.S. prescriptions.
- Using prescription data for the Medicaid estimate:
  - In 2022, just over 6.7 billion prescriptions were filled in the U.S.[7]
  - For the same year, Medicaid accounted for 756 million prescriptions[8] or approximately 11% of all U.S. prescriptions.

The estimated impact of Medicaid and PHS together is roughly one-quarter of all U.S. prescriptions and more than $37 billion in discounts.

If just 1% of total sales represents an overlapping 340B and Medicaid discount, this would mean at least $1.6 billion in duplicate discounts. In other words, for every $100 million in sales, a manufacturer could give away more than $230,000 for **every** 1% overlap.

In addition to revenue leakage, duplicate discounts can lead to penalties for noncompliance: Manufactures that knowingly overcharge for 340B drugs can face civil monetary penalties in excess of $5,000 per violation and/or termination of their Pharmaceutical Pricing Agreement, which would then exclude their drugs from Medicaid and Medicare Part B coverage.

[5] Statista. "Global pharmaceutical sales from 2020 to 2023, by region."

[6] Health Resources & Services Administration. "2023 340B Covered Entity Purchases."

[7] Statista. "Total number of medical prescriptions dispensed in the U.S. from 2009 to 2022."

[8] Kaiser Family Foundation. "Recent Trends in Medicaid Outpatient Prescription Drugs and Spending." October 11, 2024.

Identifying and avoiding duplicate discounts

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Identifying and avoiding duplicate discounts

Spotting duplicate discounts requires understanding the transactional data for both 340B sales and chargebacks, as well as prescription fulfillment and reimbursement for Medicaid patients. While manufacturers can apply many possible methods to spot duplicate discounts, below is an example of a relatively straightforward – if data-intensive – approach to illustrate the process.

1. 340B-eligible CEs and relationships – Each eligible customer purchasing at the 340B price must be an approved CE with a valid 340B identification number. Be sure to validate their physical location and any related CPs or other provider relationships.

2. Chargebacks – Examine the chargeback data:

a. **Identify any 340B purchases** – Pay particular attention to 340B chargebacks, noting purchases made by CEs and those shipped to CPs.

b. **Cross-reference for commercial purchases** – Compare the location information for your 340B purchases against your commercial purchases. Locations with commercial purchases are less likely to have double-dipping, but the difference in volume may be an indicator.

3. Product Transfer and Resale Report (EDI 867) data – Review this data, as it may identify commercial purchases that are not eligible for commercial purchase discounts (i.e., no chargeback would be submitted).

4. Medicaid claim-level detail (CLD) – Find out if your state provides CLD (you may have to make a request). The utilization data provided by the Medicaid programs will be the most lagged information, but it is used to identify two key data points:

c. Dispensing pharmacy

d. Prescribing physician or healthcare provider (HCP)

5. HCP-practice relationships – Associate physicians or prescribing HCPs with any CEs from which they practice to help identify higher potential for duplicate discounts.

Transactions with the highest likelihood of duplicate discounts include these criteria:

1. Medicaid rebate claims where the prescription was written by an HCP associated with a CE provider location
2. Medicaid rebate claims where the prescription was dispensed by a CP or CE
3. A CP or CE that predominantly or exclusively purchases at the 340B price

How Model N can help

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How Model N can help

Through our industry-leading combination of advanced technology and expert services, Model N helps manufacturers navigate the complicated landscape of the 340B Drug Pricing Program and avoid double dipping.

Model N 340B Vigilance helps manufacturers reduce the likelihood of duplicate discounting within the 340B Drug Pricing Program that leads to downward pressure on revenues. This add-on module to Model N Validata, our industry-leading automated script-level validation tool, contains options that leverage risk assessment algorithms from a leading third-party 340B consultancy or access to definitive 340B prescription transaction data collected from a third-party service to identify submitted script transactions that have a high likelihood of being dispensed with product acquired at a 340B price.

Model N Advisory Services offers strategic and operational consulting to help you analyze your existing pricing and data to understand your double-dip risk. We can also suggest and implement solutions to capture and dispute duplicate discounts, regardless of the software you currently use.

Ready to protect your revenue and reduce the risk associated with duplicate discounts?

About Model N

Model N is the leader in revenue optimization and compliance for pharmaceutical, medtech and high-tech innovators. For 25 years, our intelligent platform has powered digital transformation for pharmaceutical, medtech, and high-tech companies with integrated technology, data, analytics, and expert services that deliver deep insight and control.

Our integrated cloud solution is proven to automate pricing, incentive and contract decisions to scale business profitably and grow revenue. Model N is trusted across more than 120 countries by the world's leading companies, including Johnson & Johnson, AstraZeneca, Stryker, SeagateTechnology and Microchip Technology.
For more information, visit **modeln.com**

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