

# Address the 340B duplicate discount problem

In the complex ecosystem of the pharmaceutical industry, various pricing models can significantly impact manufacturers' revenue streams. One such model, the 340B Drug Pricing Program enables providers to improve patient care through access to drugs at significantly lower costs. Outlined in the Pharmaceutical Industry Contracting Organization contract, drugs dispensed by providers who acquired them at 340B discounted pricing are, in many cases, ineligible for rebate payments. However, manufacturers have had trouble verifying whether rebate claims include prescriptions that were dispensed using product acquired at 340B prices, which means they're often paying "duplicate discounts."

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.

## Integrations with third-party service providers

340B Vigilance integrates with Berkeley Research Group (BRG) and CiiTA to assist in the identification of duplicate discount script transactions. Depending on the third-party service a manufacturer uses, the process differs. Here's an overview of how each one works.

### BRG

Through the automated integration with BRG, definitive 340B script transaction data submitted to BRG by covered entities (CEs) on behalf of the manufacturer is accessible by the out-of-the-box validation within Validata. To validate a commercial or Medicaid submission, Validata applies a specific rule set to match key data elements on the submission utilization lines with the BRG-provided data. If a match is found, an error code is assigned to the line, which indicates the script was acquired at the 340B price and is ineligible for a rebate.

BRG regularly updates the data; however, CEs can take up to 45 days to submit 340B script transactions to BRG. This means that manufacturers may still pay duplicate discounts if a match was not found during the validation process. Through additional reprocessing capabilities, 340B Vigilance creates batch evaluations to run routinely on a subset of submissions. When BRG data is updated, more matches can be identified on a published or paid submission. If matches are found in the batch evaluation process, relevant lines are identified as 340B reversals.

# \$34B

to \$37.5B of sales at wholesale acquisition cost pricing could be subjected to a duplicate discount.<sup>1</sup>

## CiiTA

Rather than being based on definitive 340B script transaction data, the CiiTA integration and related validations run inbound payer submission content through CiiTA-developed risk assessment algorithms to predictively identify potential 340B duplicate discount transactions. Files included in a submission can be marked (opted-in) for 340B evaluation, where the data is run through the associated risk assessments within the Model N cloud. The risk assessments evaluate various aspects of the transaction against Medicaid exclusion file (MEF), prescriber-related, and pharmacy-related algorithms. Risk assessment findings are used to update the script transaction data within Validata based on error severity assignments for scripts that are probable to have been dispensed using product acquired at 340B prices. To ensure compliance with service-level agreements, email alerts provide updates on the progress and outcomes throughout the process.

## Definitive transaction data submissions

After 340B Vigilance uses this third-party data to flag ineligible scripts and identify duplicate discounts, corrective actions can be taken to improve the 340B program integrity. Should there be a difference of opinion between the CE and the manufacturer concerning the eligibility of a prescription, a good faith initiative can be initiated to resolve the issue.

## Enhanced checks and reporting

340B Vigilance expands the validation capabilities – including 340B duplicate discount checks – that are already performed within Validata, enabling more accurate identification of ineligible rebate claims. All results are available in the Validata dashboard. Also provided are summaries of 340B duplicate discount assessments, reports on integrated validation errors, and seamless National Council for Prescription Drug Programs (NCPDP)-compliant reconciliation (RD) file generation with 340B-related reconciliation reason codes.

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<sup>1</sup> IQVIA. “Can 340B modifiers avoid duplicate discounts in the IRA?” February 21, 2023.

## Ineligible service provider identification





Through this feature, manufacturers can ingest and maintain a control list of pharmacies or service providers – either alone or in combination with specific products – that they deem ineligible for rebates. During validation, script utilization data is compared to the ineligible service provider control list. If a service provider ID or service provider ID and product service ID combination matches the control list, an error is assigned, and the script is removed from rebate eligibility.

## A robust 340B validation solution

Active users of Model N Payer Management, Model N Medicaid, and Validata can add 340B Vigilance to their solution suite to further reduce the potential of lost revenue. When used together, these powerful applications help ensure that all rebates paid out of Payer Management and claims paid through Medicaid are accurate.

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## Optimize revenue with 340B Vigilance

-  Identify prescriptions that may have been subjected to a duplicate discount.
-  Continuously monitor compliance with the 340B Drug Pricing Program.
-  Reduce revenue loss caused by double or triple dipping.
-  Gain insight and control over 340B discounts.

## Efficiently manage the 340B process

Schedule a demonstration to learn how 340B Vigilance can help validate script-level data to address the duplicate discount problem with 340B.