White Paper

Understanding and Tackling the Complexities of 340B Duplicate Discount Scrubbing

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As manufacturers navigate the intricate landscape of the 340B Drug Pricing Program, the practice of claim scrubbing for 340B duplicate discounts becomes increasingly vital. This white paper will examine the specific industry concerns that manufacturers encounter, such as duplicate discounts, compliance complexities, and market dynamics, and will further explore some best practices and technology solutions currently available in the market to address these issues.

The 340B program

- The 340B Drug Pricing Program, established in 1992, enables eligible healthcare organizations to purchase outpatient prescription drugs at discounted prices to improve access for vulnerable populations.
- This program offers cost savings that enable covered entities to expand healthcare services and support underserved communities.
- Eligible healthcare organizations, including certain hospitals, clinics, and federally qualified health centers, can participate in the 340B program. These entities must meet specific criteria related to patient populations served and services provided to qualify for discounted drug pricing.
- More information on the current trends of the 340B program is available in the IQVIA blog, Trends to Watch through 2023: The 340B Drug Discount Program[1].

340B duplicate discount scrubbing

Scrubbing is the act of analyzing data for data errors or contractual compliance issues. In the case of 340B, this refers to the practice of identifying instances where covered entities or contract pharmacies bought product at the 340B price. Then, when the pharmacy dispenses product to a patient, a payor submits this claim to manufacturer for rebate payment. By many accounts and experts in the industry, products dispensed to a 340B patient, should not be subject to a payor (commercial or state) rebate. This is known as a duplicate discount. This can lead to significant financial losses for manufacturers (see Figure 1 for details). Putting this together, 340B duplicate discount scrubbing is reviewing utilization lines or Medicaid claims level data (CLD) to identify and withhold payment to a customer for 340B filled prescriptions.

The graphic below illustrates a typical case of 340B duplicate discount which results in the manufacturer losing money on a product dispense.

Figure 1: Simple breakdown of 340B duplicate discounts on manufacturer's finances

DATE	EVENT	$ AMOUNT	GTN FOR MANUFACTURER
May 10	Box is purchased at List Price (WAC) by Wholesaler XYZ	$100	**$100**
May 18	Covered Entity (CE) buys and/ or Contract Pharmacy (CP) recieves box from XYZ at 340B Discount Price of $34	$34	
May 19	Chargeback is issued to Wholesaler	-$66	**$34**
June 12	340B Patient has prescription filled. Presents Insurace Card indicating coverage. Utilization transaction is recorded here	$10 Copay $24 Payer	
July 01	Payer sends eligible June prescriptions to Manufacturer requesting 40% rebate off WAC		
July 30	Manufacturer does not have tools or processes in place to identify this transaction as a duplicate and pays rebate to payer	-$40	**-$6**

Duplicate Discount

Challenges in scrubbing for 340B

Challenges of 340B scrubbing include accurately identifying eligible patients, ensuring compliance with program requirements, maintaining auditable records, and addressing concerns related to the diversion of 340B drugs. Additionally, the increasing scrutiny of covered entities, financial implications, and limited accessibility for eligible patients pose additional challenges in effectively implementing and managing the 340B scrubbing process.

CHALLENGES OF 340B SCRUBBING FROM DIFFERENT PERSPECTIVES:

1. Manufacturer Concerns

- *Duplicate discounts*: Manufacturers face the challenge of encountering potential duplicate discounts in which the covered entity gets an upfront discount and the claim submitter (pharmacy benefit manager (PBM) Medicaid/Medicare) receives a back-end rebate for the same prescription, leading to financial losses. This is sometimes referred to as 'double dipping.' Based on research and studies, a staggering $34.0B to $37.5B of sales at wholesale acquisition cost (WAC) pricing may be at risk for IRA/340B duplicate discounts[2]. To identify these claims correctly, manufacturers must navigate the complex process of identifying pharmacy eligibility and compliance monitoring. Due to a lack of regulations, there are no clear indicators to tie out data across different channels/sources, making it even more difficult to spot double dipping or duplicate discounts.
- Co*mpliance complexities*: As the scrutiny around the 340B program grows, there have been instances where the discounts provided to covered entities are perceived as a form of kickbacks to PBMs. This issue raises concerns about the transparency and fairness of the program, as well as the potential for conflicts of interest.
- *Unclear regulations*: Manufacturers express concerns about the lack of clear regulations and enforcement mechanisms, making it difficult to ensure proper compliance by covered entities. The onus falls on the manufactures to navigate through these compliance concerns and ensure the 340B program is functioning in accordance with legal and ethical standards.
- *Diversion and market dynamics*: Diversion and its impact on market dynamics is another significant concern for manufacturers in the context of the 340B program. Diversion refers to the unauthorized distribution or use of 340B drugs outside the intended patient population or covered entity. This practice can disrupt the normal flow of drugs within the market and lead to unintended consequences. This raises ethical concerns and may prevent those who genuinely need the medication from accessing it at an affordable price.

  Moreover, diversion can disrupt the fair competition and market dynamics within the pharmaceutical industry by distorting market pricing and impact the overall availability of medications.

2. Covered Entity Challenges

- *Compliance burden*: Covered entities face complexities in meeting program requirements, maintaining auditable records, ensuring accurate patient eligibility, and establishing robust internal control systems.
- *Regulatory scrutiny*: Increased scrutiny by regulatory bodies places greater emphasis on compliance, with potential penalties for violations, adding to the challenges faced by covered entities.
- *Financial implications*: The administrative costs associated with maintaining compliance and managing the program can strain covered entities' financial resources.

3. Patient Perspective

- *Limited accessibility*: Eligible patients may face challenges accessing affordable medications through the 340B program, potentially limiting their ability to obtain necessary treatments.
- *Lack of transparency*: Patients may have concerns about the transparency of 340B pricing and the extent to which they directly benefit from the cost savings generated by the program.

Addressing these challenges from various perspectives is crucial to ensure the effective implementation of 340B scrubbing practices and optimize the program's potential for manufacturers, covered entities, and patients alike.

Best practices for 340B scrubbing

When it comes to best practices for 340B scrubbing, manufacturers play a crucial role in ensuring program integrity and compliance. By implementing robust eligibility verification processes and fostering transparent communication, manufacturers can contribute to the effectiveness and fairness of the 340B program.

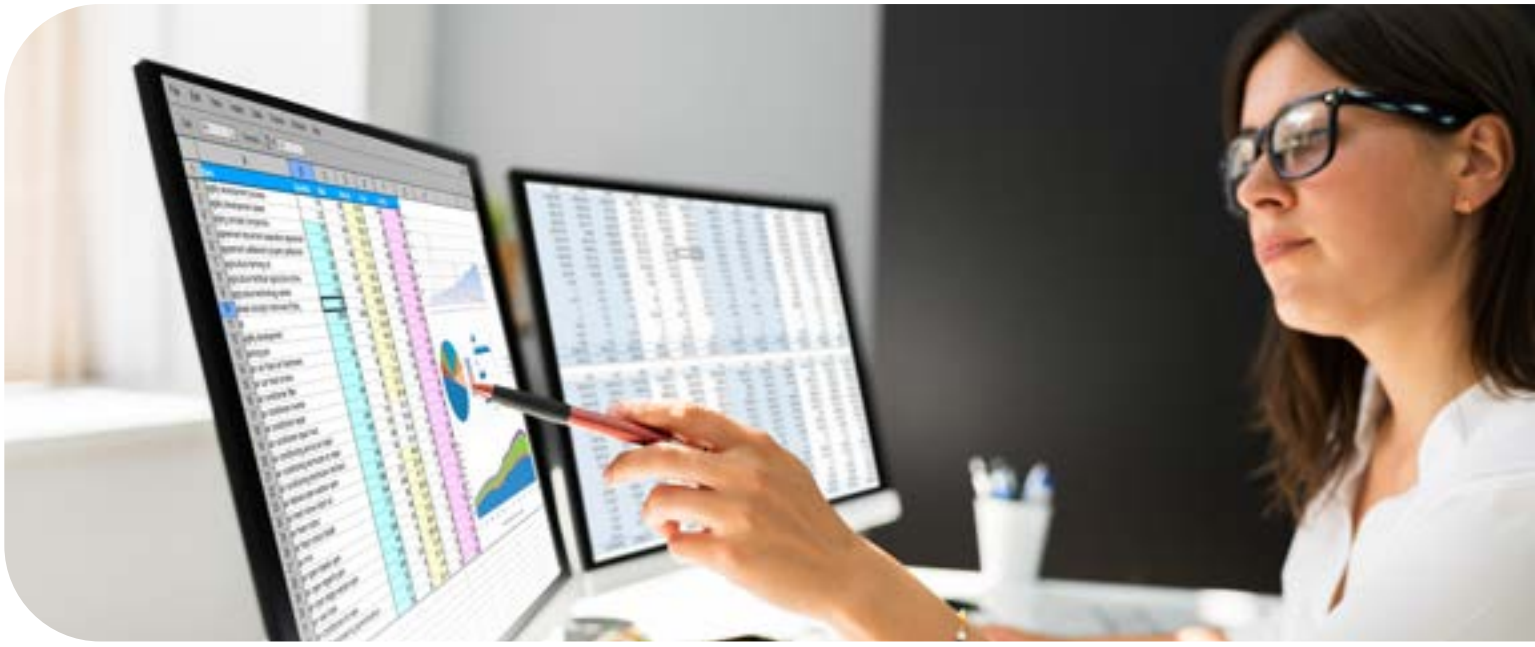
- *Robust data management*: Eligibility verification in the context of the 340B program can involve assorted options and techniques. One option is to utilize NCPDP (National Council for Prescription Drug Programs) indicators as part of the verification process. NCPDP provides standard codes that can support identifying specific eligibility criteria for pharmacies and prescriptions. Incorporating these in confirming patient eligibility can reduce the risk of improper utilization of the 340B program discounts.

  It is important to stay updated with the latest NCPDP code sets and guidelines to effectively implement eligibility verification procedures.

- *Eligibility verification platforms*: Third-party eligibility verification platforms provide access to patient eligibility information and help manufacturers validate patient eligibility during the scrubbing process. These platforms integrate with external data sources, such as Medicaid and Medicare databases, to ensure accurate and up-to-date eligibility determinations.

- *Compliance monitoring and auditing solutions*: Compliance monitoring and auditing solutions help manufacturers ensure adherence to 340B program regulations and identify potential compliance issues. These tools analyze data, perform audits, and generate reports to detect anomalies, monitor program compliance, and address any non-compliance risks promptly.

Overall, validation and scrubbing can happen at various levels, such as pharmacy, patient/physician, or even deeper, depending on the desired depth of scrutiny and available resources. Pharmacy-level scrubbing offers cost-effective eligibility verification at a prescription level, while patient/physician-level scrubbing involves a more comprehensive assessment of patient data, including demographics, insurance information, and physician prescribing patterns, to ensure accurate eligibility determination. Manufacturers should consider their goals, available data sources, and resource allocations when determining the appropriate level of scrubbing.

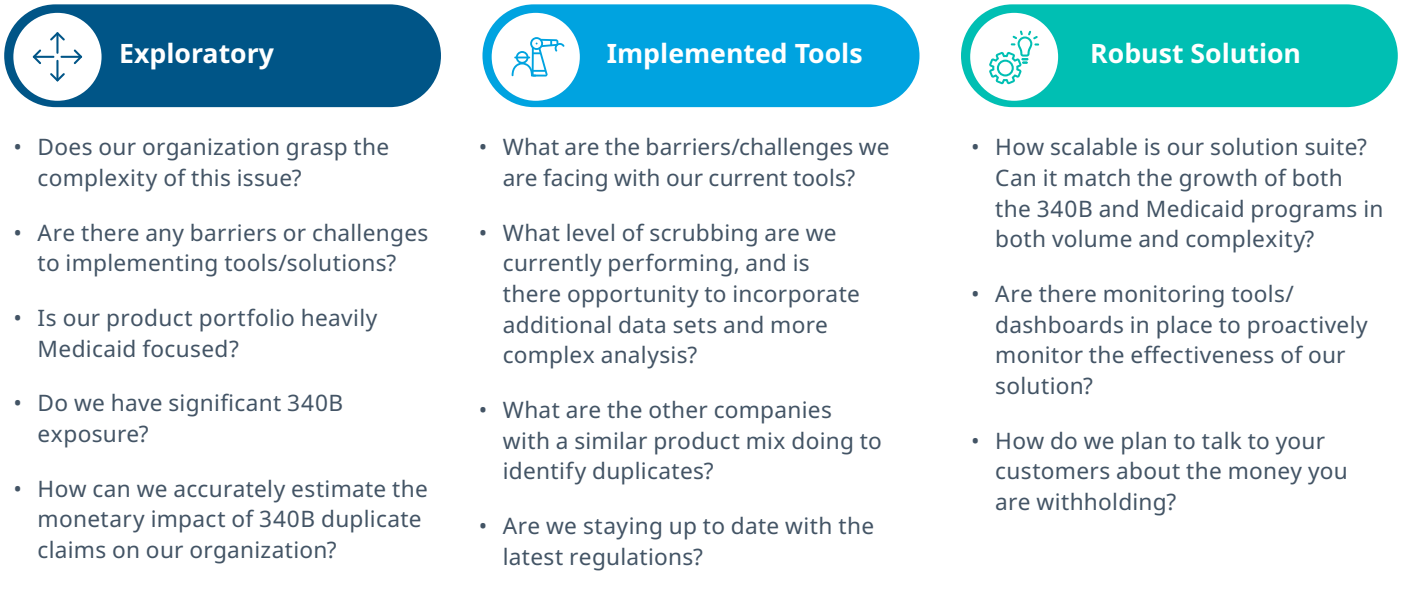


Conclusion

340B duplicate discount scrubbing has been a hot topic in the pharmaceutical industry, and is only expected to gain further attention as regulators continue to focus on program integrity. Manufacturers must be vigilant in their efforts to address the challenges with eligibility verification, compliance, and market dynamics by embracing robust data management and technological solutions, not only for their benefit, but to support the overarching goal of improving patient access to affordable medications.

There is no "magic bullet" solution that every manufacturer must have in place. Instead, it is imperative that the solutions be thoughtfully tailored to each manufacturer's capabilities, exposure risk, and available resources. The questions provided in the figure below can help catalyze these discussions within your organization when contemplating the best path forward.

Figure 2: Questions to consider based upon current organizational level of maturity in identifying 340B duplicates



IQVIA's Global Pricing & Contracting team is available to partner with your organization to accomplish strategic objectives across the revenue management space, including the implementation of tools and solutions for 340B duplicate discount scrubbing. Learn more about our capabilities here.

For additional information on this topic, contact kunal.akwalia@iqvia.com

References

1. https://www.iqvia.com/locations/united-states/blogs/2022/03/trends-340b-drug-discount-program
2. https://www.iqvia.com/locations/united-states/library/white-papers/can-340b-modifiers-avoid-duplicate-discounts-in-the-ira

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Prakhar Singh is a Senior Consultant for Global Pricing and Contracting within IQVIA's Market Access Center of Excellence. Prakhar's area of expertise ranges across the Commercial and Managed Care domain. Over his years in the healthcare industry, Prakhar has focused on system process design and technology implementation across all phases of a project.

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