CiiTA Monograph Series

340B/MEDICAID DUPLICATE DISCOUNT RISK TO MANUFACTURERS

EXECUTIVE SUMMARY

A duplicate discount occurs when inventory subject to a 340B Program discount is also submitted for a Medicaid rebate, causing the drug manufacturer to pay two discounts on the same drug. This has significant impact on revenue models and can often cause the drug to be "sold" below cost. In recent years, three principal forces have contributed to the growth of this risk: 1) the expansion of the Medicaid rebate to include both Managed Medicaid and Fee-for-Service; 2) the participation of contract pharmacies and program administrators who are unfamiliar with duplicate discount risk; and 3) the continuing lack of regulatory guidance regarding a standard mechanism for preventing duplicate discounts.

The 340B Program statute clearly both prohibits duplicate discounts and assigns responsibility for duplicate discount prevention to covered entities. The Medicaid statute also puts some responsibility for Managed Care Organization (MCO) claims for duplicate discount prevention on the states, possibly because a significant portion of Medicaid patients receive services from 340B covered entity providers.[1] The ability of either covered entities or even states to meet this responsibility, however, is severely limited. Given that virtually all large 340B Programs are managed by third-party administrators, most covered entities do not have complete visibility into their own 340B Program operations, much less an awareness of potential overlap with Medicaid rebate requests. This lack of transparency is further exacerbated by a 340B Program claims qualification process that is isolated from other federal discount programs by a unique data set and controls. There is no standard or consistently used mechanism—regulatory or otherwise—that looks at both programs simultaneously.

The Office of Pharmacy Affairs (OPA) has audited more than 350 covered entities for 340B Program compliance since 2012. Among those audited, more than 25% were found to have duplicate discount errors. These findings suggest duplicate discounts create a material financial risk to manufacturers.[2]

BACKGROUND

Duplicate discounts are the direct result of a conflict between two federal programs: Medicaid rebates intended to benefit state Medicaid programs, and 340B discounts intended to benefit eligible safety-net providers, referred to as covered entities. Together these programs have a substantial overlap in prescription eligibility, making it possible for both states and covered entities to claim a discount for the same purchase.[3]

As noted in a recent HHS Office of the Inspector General report, the 340B Program statute clearly prohibits duplicate discounts:

> *"Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law. Duplicate discounts occur when a drug manufacturer pays a State Medicaid agency a rebate under the Medicaid drug rebate program on a drug sold at the already-discounted 340B price. The risk of duplicate discounts applies to MCO Medicaid (Managed Care Organization Medicaid) as well as traditional FFFS Medicaid (Fee For Service Medicaid) in states where drug manufacturers are paying rebates on drugs dispensed through MCO Medicaid."*[4]

In theory, 340B Program participants are expected to track and manage 340B inventory and ensure its exclusion from Medicaid rebate requests. The original control for this is referred to as the "Medicaid Exclusion File." With this file, entities notify HRSA of their intended method to reconcile 340B and Medicaid claims:[5]

- Covered entities may choose to *"carve in"* 340B claims (i.e., prescribe 340B drugs for their Medicaid patients). In the carve-in model, the entity's Medicaid provider number will be listed on the Medicaid Exclusion File. States then use this information to exclude claims with that number from the Medicaid rebate process.

- Covered entities may choose to *"carve out"* 340B claims (i.e., use non-340B drugs for their Medicaid patients). In the carve-out model, the entity's Medicaid Provider number will not be listed on the Medicaid Exclusion File, allowing claims with that number to be processed for Medicaid rebates.

The majority of covered entities choose to carve in Medicaid claims (some states mandate it) and purchase this inventory through the 340B Program. The result of this choice is that none of the consequent utilization is eligible for Medicaid rebates.[6]

In practice, the Medicaid Exclusion File proves to be an insufficient control mechanism. It was originally designed as an administration tool exclusively for Fee-for-Service Medicaid (FFS). In the FFS model, the Exclusion File was designated as a single point of control for states to identify the 340B status of prescriptions generated by a covered entity, carved either in or out. When the Exclusion File process was initiated, covered entities were limited to a single 340B contract pharmacy per service delivery site. This made the prescription qualification and rebate generation process, relatively speaking, quite straightforward.

Coincident with the ACA expansion of Medicaid rebates to managed care in 2010, the one-to-one relationship between a coved entity site and a 340B dispensing pharmacy was lifted by HRSA. Covered entities subsequently built large contract pharmacy networks throughout their service areas. These networks are typically composed of traditional retail pharmacies which dispense to all kinds of patients, only a small percentage of which are 340B-eligible.

Therein lies the primary conflict between Medicaid and 340B. Medicaid claims are adjudicated by all pharmacies at point-of-sale: at the time they are dispensed. 340B claims, however, are qualified post-adjudication, sometimes days or weeks later. The result is that Medicaid claims, and the associated rebate amounts, accumulate as they are dispensed. But by means of a parallel and asynchronous system, some of these claims are later also classified as 340B. Claims that had already been charged to Medicaid are subsequently, and erroneously, charged to the covered entity's 340B account and purchased at 340B prices.

Contract pharmacies have an administrative disincentive, and no financial motivation, to re-adjudicate these claims. Although current guidance makes covered entities responsible for duplicate discount prevention, many are unaware of the need to, or simply cannot, reconcile the Medicaid and 340B claims dispensed by their contract pharmacies. This lack of oversight results in overstated Medicaid agency rebate requests.

THE COMPLICATING EFFECT OF MEDICAID EXPANSION

Recent changes in Medicaid have substantially increased the scale and scope of 340B duplicate discount risk. As noted previously, the Affordable Care Act (ACA) extended Medicaid rebate eligibility to include drugs dispensed under MCO plans. HRSA also lifted the restriction specifying a one-to-one relationship between a covered entity and a contract pharmacy. These two actions have had a number of unforeseen effects on 340B program management.

» ***The extension of Medicaid rebates to MCOs increases the overlap with 340B.***
Compelling states to claim Medicaid rebates for drugs dispensed through MCOs (instead of just FFS) significantly increases the total number of Medicaid rebate claims, and the potential overlap with 340B. The overlap is exaggerated in part because states show signs of expanding their use of MCOs to cover the Medicaid pharmacy benefit. This expansion in rebate claim volume increases the likelihood that state Medicaid offices will request rebates for drugs already purchased at 340B discount.

» ***A proliferation of third parties has increased the complexity of program management.***
The profit potential of the 340B Program has attracted many third-party participants. Most covered entities now have extensive contract pharmacy networks and outsource their 340B Program implementation and operation to third-party administrators who do not share a common understanding of claim management, and whose systems are designed to qualify claims post-adjudication. Many do not adjust for, or even recognize, the carved out Medicaid claims that should be reversed.

» ***Lack of visibility into the full claims set hinders oversight.***
Prevention of duplicate discounts requires an automated process to continuously monitor and differentiate prescription claim status. But as noted previously, the processing of 340B and Medicaid prescriptions splits at the point of sale, when the data sets become independent and are managed by separate parties for different purposes. Pharmacies have one view to manage their inventory. Covered entities, along with their administrators, have another view to manage 340B Program financials. And state Medicaid agencies have yet another view generated by point of sale adjudication. Each data set is incomplete, and no single party can see the whole picture. There is currently no mechanism to bring the necessary data back together for purposes of duplicate discount prevention.

INCOMPLETE CONTROLS AND CONFLICTING GUIDANCE

Audits conducted by the Government Accountability Office (GAO) have found that 340B Program controls are inadequate to prevent duplicate discounts.[4] Incomplete Medicaid rebate controls, a lack of a standard accountability mechanism, and recent conflicting guidance from various regulatory agencies and legislation have combined to create confusion around the responsibility for preventing duplicate discounts. Original guidance states that "covered entities must have mechanisms in place to prevent duplicate discounts" in the context of their contract pharmacy arrangements.[5] But as documented above, that responsibility has proven difficult to manage.

Although the ACA reinforced the mandate prohibiting duplicate discounts, it did not explicitly assign accountability for ensuring against this risk for MCO claims. This led to a significant amount of "finger pointing" between the relevant parties—and exposed the underlying issues relevant to mitigating duplicate discounts for MCO claims. In an attempt to resolve this, HRSA has proposed through its mega guidance that final responsibility for prevention of MCO duplicate discounts lies with the MCO. CMS also made this clear with its proposed regulation released June 1, 2015.[7] However, neither CMS nor HRSA have direct authority over Medicaid MCOs. Clearly, putting duplicate discount prevention in the hands of hundreds of MCOs, each with its own unique control system, is problematic. As is the case throughout the complex 340B process, many of these MCOs lack effective systems to identify and exclude 340B claims from state Medicaid rebate requests.[8]

THE PROFIT POTENTIAL OF 340B

While not related to Medicaid duplicate discount risk per se, there is evidence that participation in 340B affects prescribing behavior among participating safety net hospitals. According to data published in *Health Affairs,* 340B covered entities prescribe generics at a much lower rate than the average of all providers.[9] Conversely, covered entities dispense high-cost specialty drugs at a much higher rate than other providers[10] (see Figures 1 and 2).

The Berkeley Research Group predicts that 340B outpatient purchases of branded drugs will rise from 5.2% of sales in 2013 to 8.0% of sales by 2019.[11] A similar expansion can be expected for single source generics and specialty drugs. Given the higher concentration of Medicaid patients among 340B covered entities compared to other providers, as well as the aforementioned potential overlap of 340B and Medicaid claims, manufactures have good reason to be concerned about growing exposure to duplicate discounts.

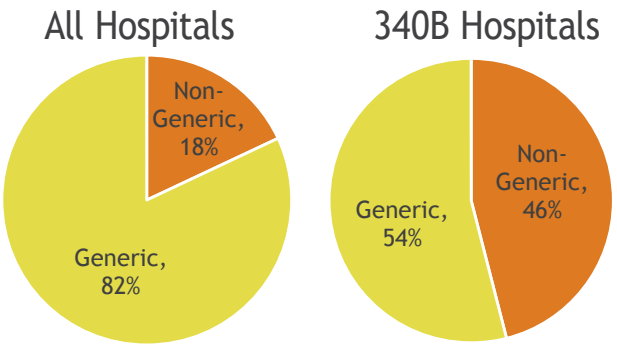

Figure 1. Generic vs. Non-Generic Dispensing Rate

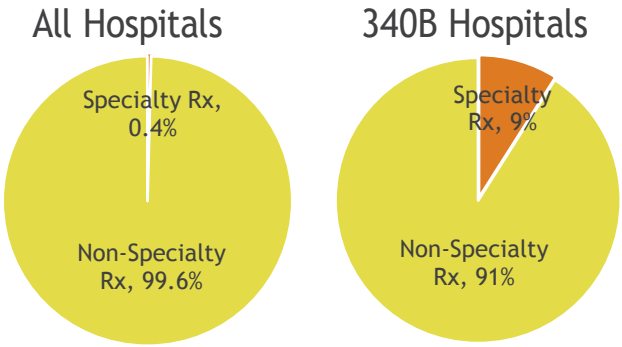

Figure 2. Specialty Rx Dispensing Rate

CONCLUSION

Regulatory oversight of the 340B Program is insufficient given the complexity of the Program. The OPA's lack of regulatory authority has allowed Program controls to become inadequate to protect manufacturers from having to pay duplicate 340B and Medicaid discounts.[12] Guidelines have not kept pace with the rapid increase in Program participation, and there is no clear mechanism in place to ensure 340B Program integrity with respect to its overlap with Medicaid.

While covered entities, and to some extent MCOs, have been identified as responsible for preventing duplicate discounts, they have failed to do so. By default this responsibility still falls to manufacturers. In order to effectively detect duplicate discounts, manufacturers must be review detailed data for drugs purchased at 340B prices and compare it to state Medicaid rebate claims data. Current controls make this data difficult to acquire, but reconciliation of these two data sources is necessary to mitigate the financial exposure.

Fortunately, Program guidelines have repeatedly affirmed manufacturers' authority to review 340B Program implementations, dispute Medicaid rebate claims suspected of being erroneous, and seek remediation if duplicate discount errors are discovered. Manufacturers must exercise this authority if they are to take control of their duplicate discount risk.

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2. CMS Hospital database. https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year-Items/HOSPITAL10-DL-2013.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=ascending
3. Three key pieces of legislation define the relationship between 340B discounts and Medicaid rebates: (a) The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) created a discount price structure allowing states to claim rebates for "traditional" Fee-For-Service (FFS) Medicaid drugs. (b) The Veterans Health Care Act of 1992 created a discount pricing structure that allowed covered entities to purchase drugs at a reduced price (340B discount). It also recognized a financial risk to manufacturers and legislated that manufacturers will not be required to pay both a 340B discount and a Medicaid rebate. (c) The Affordable Care Act of 2010 expanded state Medicaid rebates to include drugs dispensed under MCO plans.
4. "Contract Pharmacy Arrangements in the 340B Program (Report OEI-05-13-00431)." Office of the Inspector General, DHHS. http://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf
5. Medicaid Exclusion File/Duplicate Discount Prohibition. http://www.hrsa.gov/opa/programrequirements/medicaidexclusion/
6. (extracted from the Medicaid exclusion file and CMS cost report data)
7. "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability." Federal Register; June 1, 2015. http://www.gpo.gov/fdsys/pkg/FR-2015-06-01/pdf/2015-12965.pdf
8. Broadly speaking, Medicaid care is covered by two payment mechanisms: the original mechanism is a patient-by-patient billing reflecting a standard plan where states function as care plan managers. This put the states "at risk" for Medicaid. In an attempt to manage this risk, states started collecting high-risk patients and putting them in pools and reinsuring these pools through secondary providers, MCOs. Due to cost management pressures, the use of MCOs has risen from insignificant levels two decades ago to the point where they are now: the majority of Medicaid care.
9. Bobby L. Clark et al., "The 340B Discount Program: Outpatient Prescription Dispensing Patterns Through Contract Pharmacies in 2012," *Health Affairs* 33 (November 2014): 2012-2017; doi:10.1377/hlthaff.2014.0833
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Our company provides unique expertise and actionable market intelligence to pharmaceutical and biotechnology manufacturers participating in the 340B Drug Discount Program. We apply in-depth knowledge of 340B Program regulations and custom research to help manufacturers mitigate the financial risk of the 340B Program on their business.