EXECUTIVE SUMMARY

The number of ineligible prescriptions purchased through the PHS 340B Drug Discount Program represents an increasing financial risk to pharmaceutical manufacturers. Purchases of 340B drugs are deeply discounted and have a material impact on net revenue for products with substantial 340B volume. CiiTA modeling indicates that as much as 10% to 15% of 340B purchases may be ineligible under current Program guidelines. Furthermore, the total value of the 340B Program in 2012 was reported by Health Resources and Services Administration (HRSA) to be $6.9 billion. The Berkeley Research Group predicts that the Program will double in size by 2019, estimating a compound annual growth rate of more than 12%. The majority of this new growth will be driven by increased hospital participation.

Inconsistent interpretation of Program guidelines, unregulated third parties acting as Program administrators, and outright Program abuse all serve to increase ineligible 340B purchases. These ineligible purchases, coupled with accelerating program growth, result in material revenue losses to manufacturers. Additionally, manufacturers are at increased risk of paying a Medicaid rebate on drugs purchased at a 340B discount due to the Medicaid rebate expansion precipitated by the Affordable Care Act (ACA).

Industry-wide, ineligible 340B purchases could easily exceed $1.5 billion per year by the end of 2015.
BACKGROUND

The PHS 340B Drug Discount Program was created in 1992 as part of the Veteran’s Health Care Act “to stretch scarce federal resources as far as possible, reaching more eligible patients, and providing more comprehensive services.”

The potential extent of the 340B Program was not fully anticipated in the legislation, and the significant ambiguity and lack of regulation around its implementation has become an issue for pharmaceutical manufacturers. In the simplest model, eligible safety net providers (referred to as “covered entities”) purchase drugs at deep discounts and dispense those drugs to eligible outpatients. Recent covered entity 340B implementations have expanded beyond this model.

While most covered entities strive for compliance with Program guidelines and regulations, the significant difference between retail price and 340B cost creates an opportunity for covered entities and other third parties to exploit the Program for financial gain via complex implementations. Covered entities routinely outsource the tracking and qualification of insured 340B prescriptions to contract pharmacy service administrators (CPSAs) whose primary expertise is the ability to manage large 340B contract pharmacy networks. The extended networks result in a sizable increase in the number of prescriptions purchased by covered entities at 340B cost and resold to insured patients at standard reimbursement rates.

The opportunity to purchase drugs at a deep discount and resell them at retail prices creates a potential for profit. For many covered entities, 340B has become a significant supplemental revenue source.
340B PROGRAM GROWTH

Early 340B Program utilization was limited and manufacturer risk was contained. However, recent changes in scale and scope have resulted in a dramatic increase in 340B purchasing. Covered entities are extending their participation via contract pharmacy networks, Program expansion, and the purchase of specialty clinics for the sole purpose of purchasing specialty prescriptions through the 340B Program.

The Berkeley Research Group predicts 340B purchases of non-Medicaid outpatient branded drugs will rise from 5.2% of sales in 2013 to 8.0% of sales by 2019 (see Figure 1). A similar expansion can be expected for single source generics and specialty drugs.

The growth in 340B Program sales directly increases the risk of noncompliant chargebacks and rebates due to covered entity misuse and abuse.

RISK FROM 340B PROGRAM MISUSE AND ABUSE

Existing 340B legislation has two primary safeguards in place to protect manufacturer interests: (1) covered entities are prohibited from submitting drugs purchased through the 340B Program for additional Medicaid rebates, i.e., no duplicate discounts; and (2) covered entities must ensure that 340B drugs are not diverted to ineligible patients. However, controls for managing these safeguards have proven to be insufficient and problematic.
**Duplicate Discount**

Duplicate discounts occur when a drug is subject to both the 340B discount and a Medicaid rebate, effectively requiring a manufacturer to pay two discounts on the same drug. While duplicate discounts are prohibited under the 340B statute, this provision is difficult to administer and therefore poorly enforced. Several factors make it difficult to effectively manage duplicate discount risk:

**Medicaid Rebate Expansion**

Historically, Medicaid rebates were generally limited to Fee-for-Service (FFS) Medicaid programs. In 2010, the ACA extended federal Medicaid rebates to cover Managed Care Organizations (MCOs). This increased the scope of Medicaid rebates by a factor of three, well past the limit of what many administrative systems could manage, directly impacting risk to manufacturers.

**Incomplete Medicaid Controls**

Today, covered entities use the Medicaid Exclusion File to account for FFS Medicaid drug utilization; i.e.: whether they will carve-in or carve-out of 340B purchases. Proposed guidance from HRSA directs covered entities to use the exclusion file for Medicaid MCO utilization as well. However, HRSA offers the proviso that covered entities may make different carve-in and carve-out decisions for each class of patients (FFS or Managed Care) and for each MCO. In addition, Centers for Medicare and Medicaid Services (CMS) has proposed that duplicate discount prevention be the responsibility of the MCOs. Given that there are more than a hundred MCOs and duplicate discount prevention is difficult to administer, this added complexity will likely lead to more errors at manufacturers’ expense.

**Focus on High-Cost Drugs**

Covered entity 340B practice is increasingly targeting higher-cost, single-source generics and brand drugs in order to capture the potential profit. This increases the financial risk to manufacturers when duplicate discount occurs.

Office of Pharmacy Affairs (OPA) audits report that more than 25% of 340B Program implementations have duplicate discount errors. Audits performed by the Government Accountability Office (GAO) document that controls are inadequate to prevent duplicate discounts. These results indicate that duplicate discount risk to manufacturers is high.
Diversion
A primary requirement of covered entity participation in the 340B Program is the prevention of drugs purchased at 340B prices from being diverted to ineligible patients. According to a GAO report on 340B, “HRSA's current guidance is not specific enough to define the situations under which an individual is considered a patient of a covered entity for purposes of 340B.” This lack of guidance makes it possible for covered entities and for-profit third parties to generate 340B revenue from ineligible patients. 2014 estimates indicate a 340B diversion rate as high as 10% to 15% of total 340B sales, or approximately $800M to $1.2B. Several factors contribute to diversion:

Misfeasance
Vague 340B Program guidelines and inadequate enforcement of reporting requirements allow covered entities and third-party administrators to develop their own interpretations of patient eligibility. This, combined with the difficulty of accurately linking patient care records to qualified services, puts manufacturers at risk of paying discounts on unqualified prescriptions.

Contract Pharmacies
Initially, covered entities had very limited 340B Program distribution options. With the lifting of the single-pharmacy restriction in 2010, covered entities gained the opportunity to create large contract pharmacy networks.

These networks, encompassing many unique implementations of 340B and interpretations of patient qualification, directly increase the potential for diversion and dispensing errors.

Malfeasance
Although the vast majority of covered entities make a good faith effort to comply with 340B regulation, in limited cases a conscious disregard for 340B guidelines results in Program abuse.

Such malfeasance occurs in at least two distinct activities, which may increase diversion of ineligible claims at manufacturers’ expense:

- Covered entities claiming care events for which they had no medical involvement; and
- Third-party administrators and contract pharmacies processing 340B prescriptions for which they have inadequate care records.
The current range and reach of the 340B Program—$12B in 2015 and growing—was never envisioned by the original legislation. Further, the Program was never intended to be a principal revenue generator for multiple for-profit companies such as third-party administrators, pharmacy benefit managers (PBMs), and health plans.

For-Profit Participants
Covered entity 340B Program implementations are complex in terms of patient identification and purchase verification. Third-party administrators address this complexity by offering proprietary services to support extended contract pharmacy relationships.

It is not uncommon for large covered entities to have relationships with several pharmacy administrators, each with their own interpretation of claim qualification. As a result, manufacturers are required to provide discounts for prescriptions based on a range of different qualification criteria, making it virtually impossible to assure the compliance of 340B purchases.

Cash Flow to Third Parties
Due to the substantial profit margins generated by 340B and a narrow loophole in antitrust laws, third-party administrators have recently created focused programs to connect payers, pharmacies, and specialty clinics in closed systems. These systems drive high-cost prescriptions through a covered entity’s 340B Program and “share the savings” among all participants. In such cases, a portion of the 340B discount paid for by manufacturers is captured by for-profit health plans and other payers. This directly conflicts with the Program’s original intent to help covered entities provide for underserved patient populations.

Purchase of Specialty Practices
Covered entities are expanding the scope of their 340B utilization through the purchase of high-cost specialty clinics such as hemophilia and oncology. The prescriptions written by these acquired clinics are then eligible for a 340B discount, and the covered entity captures the resulting revenue. This scenario exemplifies an increasingly common for-profit mindset.

A recent article in the New York Times reported that, “a single oncologist might use $2.5 million to $4 million in drugs a year. If those drugs can be acquired for a 25% discount, that is a potential profit [for the covered entity] of up to $1 million.”
CONCLUSION

More than 2,100 hospitals are currently enrolled in the 340B Program, including 45% of Medicare acute-care hospitals. This represents only half of all eligible hospitals, and the number is rising. The 340B Program has many safeguards designed to protect manufacturer interests. Unfortunately, broad interpretation of Program guidelines and insufficient oversight of Program implementation, coupled with increased participation and the large potential for profit, create a substantial risk of undetected diversion and duplicate discount. Material issues also exist with respect to patient definition, claims qualification, inventory control, and reporting. Together, these issues create a significant financial risk to manufacturers.

Legislation gives manufacturers the right to review 340B Program implementations to ensure the discounts provided are justified and in full compliance with regulatory guidelines. In the absence of other effective advocates, it is essential that manufacturers assume more active management and oversight of their 340B Program risk.

1. 2013 CiiTA modeling
4. 2013 CiiTA modeling
5. Health Resources and Service Administration, 340B Drug Pricing Program; http://www.hrsa.gov/opa/index.html
10. 2013 CiiTA modeling
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.