340B DRUG PRICING: CHALLENGES AND BEST PRACTICES

Robert Blank,
Managing Consultant
EVERSANA

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Enacted in 1992 by George H. W. Bush, the 340B Drug Pricing Program was intended to, "…stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program, named for the section of the Public Health Service (PHS) Act in which it is authorized, achieves this goal in many respects.[1] However, for all its successes, it has also become notoriously difficult to manage for the more than 600 pharmaceutical companies enrolled.[2] Data validity, crossover between lines of business, and conflicting regulations each serve to complicate matters in the revenue management practices of a drug manufacturer. While a comprehensive solution has yet to be created, there are procedures that can be undertaken to reduce liability and prevent revenue leakage. Through careful management of chargebacks, managed care rebates, Medicaid rebates, and government pricing, many commonly overlooked but costly aspects of the program can be avoided by manufacturers.

340B DRUG PRICING PROGRAM BACKGROUND

340B participation is mandatory for pharmaceutical manufacturers when agreeing to take part in the Medicaid Drug Rebate Program. As part of this program, pharmaceutical companies provide sizable discounts on outpatient drugs to institutions that primarily serve vulnerable patient populations. These covered entities include disproportionate share hospitals, family planning clinics and homeless shelters, among a variety of others. Due in part to healthcare reform, the number of these participating facilities has grown exponentially in the past few years. The Deficit Reduction Act of 2005[3] added children's hospitals, while the Affordable Care Act (2010)[4] expanded coverage to four additional hospital types. As a result, what was once a safety net for a handful of covered entities now accounts for an increasingly larger portion of total drug purchases. Conservative estimates placed 340B purchases at approximately 2% of all medications bought and sold in the US by 2014[5] and 6% by 2018.[6]

The Health Resources and Services Administration (HRSA), a division of the Department of Health and Human Services, is the regulatory body charged with overseeing the 340B program and providing guidance around its administration. Through its Prime Vendor Program (PVP), for which it contracts exclusively with Apexus, HRSA is responsible for the management of membership data, establishment of distribution channels and negotiation of discount rates.

While the provision of these price deductions undeniably serves a useful purpose, frustratingly vague program administration guidelines, coupled with a lack of effective oversight, has made managing this process difficult. This is particularly true for pharmaceutical manufacturers, where the boundaries of 340B covered entities are often blurred with other forms of reimbursement, like managed care and Medicaid rebate programs. A lack of interconnectivity between this transaction data makes duplicative payments, or "double dipping," a real possibility.

EXISTING CHALLENGES

Data Validity

Ensuring the validity of incoming wholesaler submissions can pose significant challenges for pharmaceutical manufacturers. These issues are exacerbated when dealing with 340B data. For example, while the HRSA assigned 340B ID is the only official indicator of PHS price eligibility, many wholesalers tend to identify their customers and members

primarily with a Health Industry Number (HIN) or a Drug Enforcement Administration (DEA) number, a fact recognized by HRSA.[7] Since 340B pricing is often significantly lower than the wholesale acquisition cost (WAC), or even the discount rate negotiated by group purchasing organizations (GPOs), it's imperative for manufacturers to ensure that received invoices are accurate. As a result, membership analysts spend inordinate amounts of time verifying the legitimacy of indirect customer data. Even when wholesalers provide 340B information on their invoices, limitations of the source system, recipient system or EDI connectivity mean that these identifiers can be mapped in less than ideal locations in submission files or customer records.

Figure 1 – The table below shows scenarios where an invoice contains 340B IDs in non-ID related fields; in an otherwise unused address field and the end of the customer name

Customer Name	Customer ID	Address 1	Address 2
CITY MEMORIAL HOSP	1428204F3	321 N OAK RD	CAH123456-00
COMMUNITY HOSP DSH20130099	6261668F7	897 E MAPLE ST	

To help remediate some of the issues caused by these data discrepancies, manufacturers often seek outside help. Many subscribe to a handful of reference data sources, owned and maintained by third party vendors, to use as a cross reference against their system and their customers' records. While providing a good basis of comparison for manufacturers, these databases present their own challenges.

Each system uses its own internal logic for identifying and categorizing healthcare providers and as a result, the connections between them can be tenuous at best. The records can directly conflict with one another, making the process of cross referencing information more labor intensive for analysts. This is particularly true of 340B information, which is always present in the HRSA database, but frequently omitted in other data reference sources.

Figure 2 – The chart below shows how each data source may display the same customer with information that differs from one another, as well as from wholesaler invoices

Invoice	DEA ID	HIN ID	340B ID	Class of Trade	Name
Wholesaler	BA5062093		1428204F3	Ambulatory Care	Roosevelt Hospital

Data Source	DEA ID	HIN ID	340B ID	Class of Trade	Name
DEA	BA5062093			Practitioner	Roosevelt Hospital
	BS7887942			Practitioner	Roosevelt Hospital
HIN	AH8727767	531430G00		Hospital	Roosevelt Hospital
	AH8727767	531430G00		Hospital	Roosevelt Hospital
NCPDP				Acute Care	Roosevelt Hospital
HRSA			DSH010019	Disp Shr Hosp	Roosevelt Hospital
			DSH010019A	Disp Shr Hosp	Roosevelt Hospital

Matters become more complicated when attempting to determine 340B eligibility alongside GPO membership. For certain 340B covered entities, like disproportionate share hospitals (DSH), GPO membership is prohibited for the purchasing of outpatient drugs. Other entities however, are not subject to this exclusion. This means that certain indirect customers may be allowed to purchase under a GPO agreement and at the 340B discount, making careful customer management by manufacturers even more important.

Business Segment Complications

One of the more convoluted aspects of the 340B program is the crossover it has with lines of business other than indirect sales and chargebacks. Since 340B discounts are provided at the point of purchase, there's a possibility that the script dispensing the medication could be included with managed care or Medicaid invoices, which are reimbursed months after a transaction has occurred.

While covered entities are prohibited from invoicing a Medicaid rebate when 340B pricing has been provided, oversights do happen, and limited ability to cross examine "up-front" purchases from "back-end" discounts can make catching these instances more challenging. This is further compounded by the fact that Medicaid rebate data is provided to pharmaceutical manufacturers at a summarized level, excluding entity information and making traceability difficult.

Regulation Issues

In some ways, 340B policies are designed to have flexibility in their interpretation.[8] This inherent mutability, combined with oversight from a variety of government organizations, has the unintended consequence of making consistent practices more difficult for a manufacturer to establish.

In the latter half of 2015, HRSA released a proposed "mega-guidance" on administration of the 340B program.[9] The guidance itself provided clarity around some ambiguities of the 340B program; however, healthcare industry stakeholders took issue with many of the provisions, believing them to be impractical at best and in direct conflict with other legislation at worst. A federal judge had previously declared that the organization did not have the legal authority to implement binding regulations, making the legitimacy of the guidance provided – initially intended it be a mandated ruling – more questionable.[10]

THE [CHANGES] CYCLE HAS BECOME SOMEWHAT COMMONPLACE, CAUSING MANUFACTURERS TO ADAPT QUICKLY WHEN CHANGES ARISE, ABANDON PLANS WHEN PROPOSALS FAIL, AND CONTINUE TO DEAL WITH THE AMBIGUITIES IN THE INTERIM.

One such example of the contradictory nature of the ruling was in regard to the maintenance of Managed Medicaid information in comparison to 340B records. To date, there have been three acts that all have conflicting guidance about the party tasked with oversight of this information. In the 2015 proposed rule from Centers for Medicare & Medicaid Services (CMS), managed care organizations (MCOs) are cited to have the primary responsibility, while in their AMP Final Rule, they declared that states have the primary responsibility and managed care organizations have the secondary responsibility. In contrast to both, HRSA's "mega-guidance" listed MCOs as having primary responsibility and states as having secondary responsibility.[11]

Complicating matters further, HRSA's "mega-guidance" was withdrawn in 2017, eliminating the proposed changes while still leaving many questions unanswered.[12] By 2018, changes for 340B were again proposed in the American Patients First Initiative,[13] but by 2019, many of the provisions were either struck down by federal judges or withdrawn by the administration.[14] This cycle has become somewhat commonplace, causing manufacturers to adapt quickly when changes arise, abandon plans when proposals fail, and continue to deal with the ambiguities in the interim.

Possible Costs

In addition to regulatory noncompliance, manufacturers risk potential revenue leakage by not properly managing 340B eligible customers. Since PHS customers are provided substantial discounts, the resulting chargeback to a wholesaler are much higher for these entities than those covered by a GPO. Given the frequency and volume of these transactions, it can be all too easy to miss an incorrectly categorized record. Rule-based assessment of these invoices is necessary to avoid a drain on net revenue that might otherwise go unnoticed.

Figure 3 – The tables below show how the same sales transaction, reimbursed at different rates, can cause a sizeable disparity in net profits for a manufacturer

WAC	Units	Direct Sale	GPO Chargebacks	Net Revenue
$300	1,000	$300,000	$120,000	$180,000

Variance
$(66,000)

WAC	Units	Direct Sale	PHS Chargebacks	Net Revenue
$300	1,000	$300,000	$186,000	$114,000

STEPS FOR GREATER COMPLIANCE

Chargebacks and Indirect Sales

PHS eligibility status changes on a regular basis, so it's imperative for manufacturers to constantly monitor this information for accuracy. Certain entities are more prone to change than others depending on their class of trade. Hospitals, for example, need to achieve a certain ratio of Medicaid and Medicare patients treated in order to receive classification as a DSH and therefore remain eligible for 340B pricing. Entities on the border of this threshold may alternate between qualification and non-qualification, depending on the services provided during a given timeframe.

To keep up with these shifts in eligibility, manufacturers should re-validate their records after key time periods. 340B Covered Entity Registration occurs within the first fifteen days of each calendar quarter, and eligibility goes into effect the first day of the quarter following successful registration. HRSA also conducts a recertification process annually to ensure that all information in the database is kept up to date.8 Initiating an internal audit in correspondence with these events allows manufacturers to better manage transactions from these organizations.

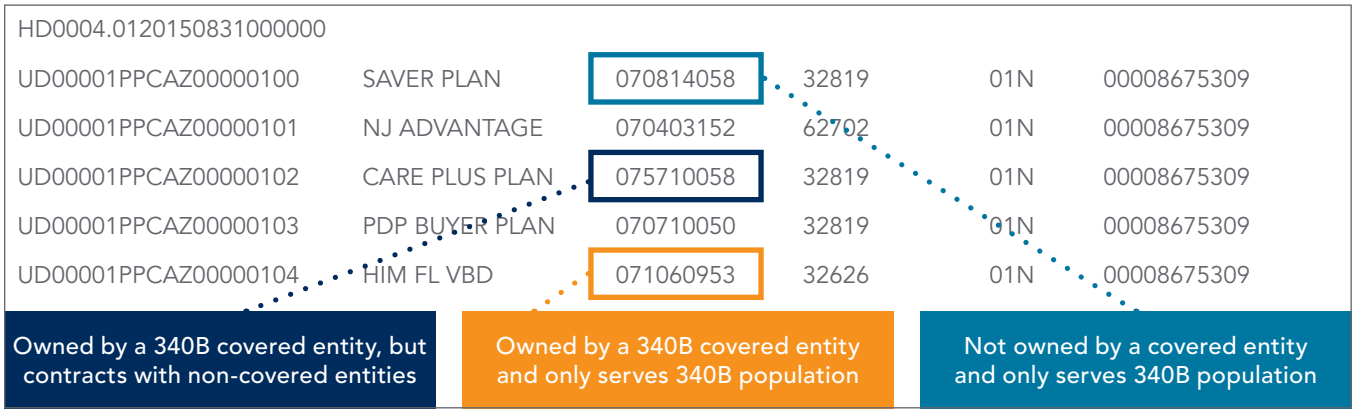
As stated before, reference databases are by no means a perfect solution and can pose significant challenges. However, when leveraged together with GPO membership rosters, they can help to provide additional clarity around indirect customer records. The two most commonly used sources are provided by the DEA and Health Industry Business Communications Council (HIBCC), which can be compared with the HRSA database to help determine 340B pricing eligibility.

Appending the identifiers from these sources to customer master data can help to streamline chargeback processing, particularly when stored in a Revenue Management System (RMS) that can validate incoming transactions against this data. While these systems typically do not have the ability to compare multiple reference databases against one another, other more purpose built membership management solutions exist that can help automate this process. Finally, in cases where the data alone does not afford a consensus on classification, proactive communication with covered entities is a good last measure for record categorization.

Managed Care Rebates

The National Council of Prescription Drug Programs (NCPDP) is a not-for-profit organization that maintains standards for healthcare provider data and offers pharmacy information on a paid basis.[15] Subscribers can access and download information for use in managed care rebate processing and analytical purposes. Used as a cross reference against invoices from pharmacy benefit managers (PBMs), a variety of data points that might have otherwise proved incomprehensible can be validated. By comparing certain identifiers, manufacturers can ascertain whether any managed care utilization is coming from 340B contracted pharmacies and can react appropriately.

Figure 4 – The image below shows how contract pharmacies can have varying levels of 340B program participation, making exclusion from Managed Care rebates more difficult



Medicaid Rebates

Manufacturers are not required to provide discounted 340B pricing and Medicaid rebates for the same transactions. Every calendar quarter, covered entities must determine whether 340B purchased drugs will be used for their Medicaid patients, a "carve-in," or if the drugs for these individuals will be acquired through other means, a "carve-out." For all entities in the former group, HRSA provides a quarterly listing of 340B covered entities that can be excluded from Medicaid rebates provided for that time period.[16] While Medicaid invoices from state agencies have summarized data by default, additional detail can be provided upon request. This claim level detail (CLD) generally contains more specific information that can be traced to the HRSA Medicaid Exclusion File and constitute the basis for a dispute. Since prior quarter adjustments (PQA) for Medicaid rebates often stretch back several months, or even years, manufacturers should download and archive each provision of the Medicaid exclusion file, as the information is updated in real time by HRSA and does not contain any history.[17]

Figure 5 – The image below shows how the Medicaid Exclusion File can be compared to Medicaid invoices to ensure that a 340B price and rebate are not given for the same drug

Medicaid Exclusion File

340B ID	NPI	Entity Name	Street Address	City
CAH121313-01	1871695271	North Hospital	123 Oak St	Oakville

Medicaid Invoice — Claim Level Detail

Rx #	NDC	Medicaid Reimb	Rebate Amt	Qty	NPI
9876542843	00008675309	$ 5,730.50	$ 2,895.13	15.00	1871695271

Government Pricing

Given the shifting nature of legislative healthcare reform, manufacturers need to be vigilant of any forthcoming changes. Some acts, like AMP Final Rule, move from proposition to law extremely slowly, giving pharmaceutical companies ample time to react and prepare for proposed changes. Others, like several of the Bipartisan Budget Acts, can seemingly get passed overnight and without much fanfare. In either case, the laws often impose significant adjustments to a manufacturer's process, so understanding the ramifications early is critical to mitigating any potential risks.

Classes of trade, for example, are typically affected by legislation regarding the 340B program. When PHS eligibility is afforded to new entities and patient populations, manufacturers need to reexamine the categorization of its existing customer records to ensure that data is grouped correctly once transactions are received and sorted into price type calculations. Many times, the newly eligible population is not covered by an existing customer type or class of trade in a manufacturer's RMS, necessitating an even more involved effort to incorporate the changes. In these cases, being proactive is often the best means of mitigating any problems before they arise.

Another way for manufacturers to stay on top of new legislation is to be vocal when changes are proposed. Oftentimes, when HRSA is considering a new position for an aspect of the 340B program, they will open a period of time for industry stakeholders to provide feedback on the suggested rule18. These windows of opportunity allow for manufacturers to not only understand the regulations, but also to ask for further clarification and challenge the propositions where necessary.

Looking Ahead

While the 340B program poses its fair share of obstacles for manufacturers, it also presents an opportunity to analyze customer and transaction data in ways that don't fit into traditional groupings, giving greater insight into the supply chain as a whole. Furthermore, if the expansions of its eligibility over the last decade are any indication, the program doesn't seem to be going away anytime soon. Though initially created to serve a few niche populations, the reach of its coverage is now far broader. As such, it benefits manufacturers to take a closer look at their processes and understand the ways in which the program can be more effectively managed, their compliance assured and their revenue preserved.

About the Author Robert Blank, Managing Consultant
Robert Blank is a managing consultant at EVERSANA, working extensively in revenue management software solutions for the pharmaceutical and medical device industries. His expertise includes Medicaid and Managed Care rebates, chargebacks, and membership management. He has developed custom client solutions around value based contracting, formulary validation, discount reallocation, and the 340B Drug Pricing Program. In his speaking engagements and published articles, Robert focuses on outlining industry trends and the impacts of legislation upon commercial operations.

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