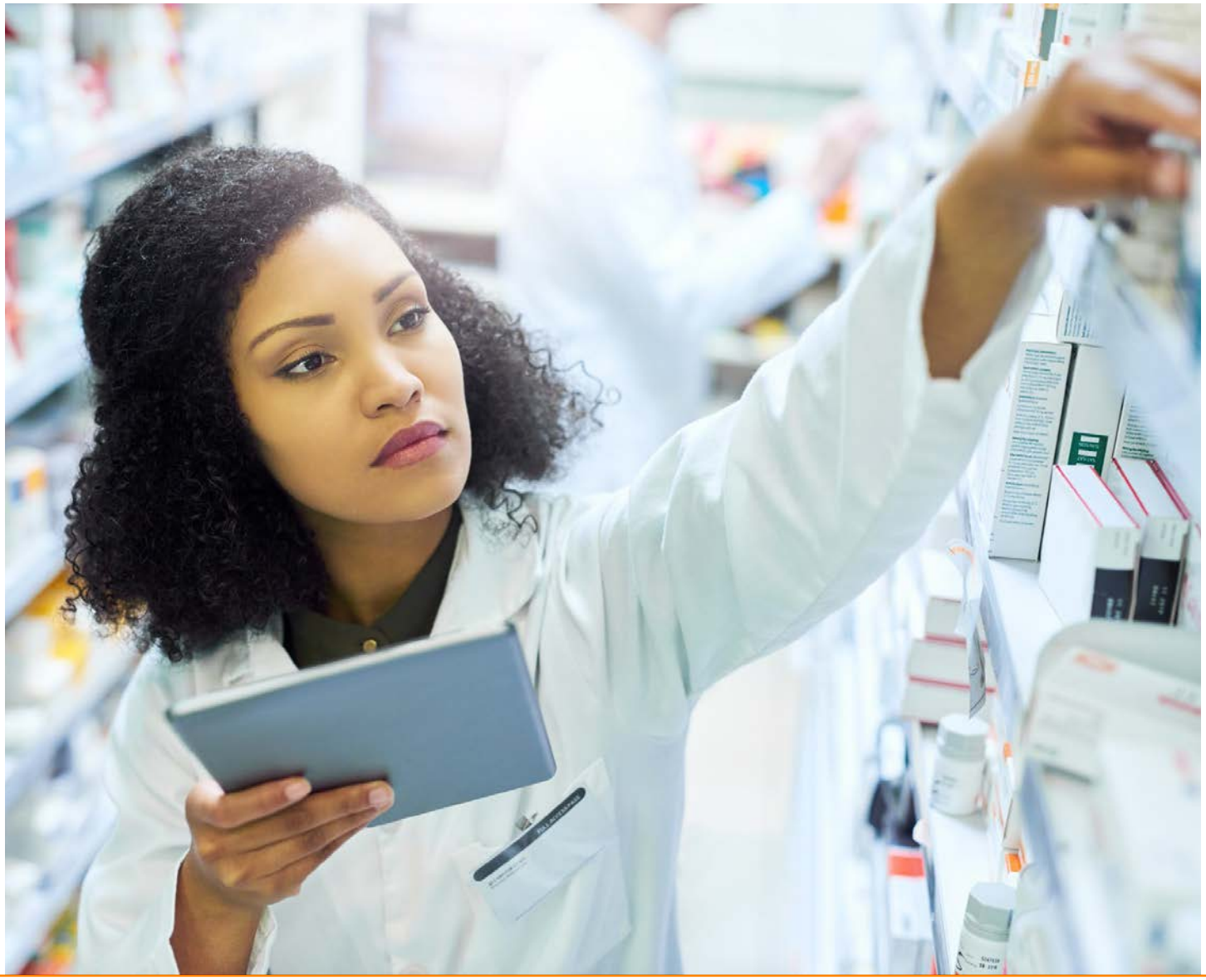


Best practices for complying with 340B

MODELN.COM

WHITE PAPER

Model **N**

The Patient Protection and Affordable Care Act of 2010 (ACA) has had sweeping ramifications on the healthcare pricing and reimbursement landscape, impacting providers, payers, manufacturers, pharmacies, and consumers. The ACA deeply altered the Medicaid Drug Program by redefining average manufacturer price (AMP), federal upper limits, and the rebate payment rates manufacturers pay to the states.

ACA also substantially modified the Public Health Service Act (PHSA) 340B Drug Pricing Program – which was originally introduced in 1992 – by expanding the definition of covered entities (CE) so that many more providers can purchase drugs at the 340B price (effectively equivalent to the Medicaid price). New program integrity provisions require manufacturers to address overcharging program participants, which has led to growth in the volume of 340B chargeback transactions and more stringent financial and legal implications for price errors.

This paper focuses on operational and systems best practices and practical approaches for streamlining 340B program management from a manufacturer's perspective and to a lesser extent channel service providers (i.e., wholesalers, distributors, and third-party logistics).

CONTENTS

Why is 340B important?

Developed to stretch scarce federal resources as far as possible, the 340B program provides comprehensive services to underinsured populations and eligible patients. Pharmaceutical manufacturers support the program's purpose, but they want to see the program properly managed so that only intended patients receive 340B discounts.

Under section 340B of the PHSA, pharmaceutical manufacturers must enter into a pharmaceutical pricing agreement (PPA) with the Department of Health and Human Services (HHS). In the PPA the manufacturer agrees to provide its outpatient drugs to CEs – providers that serve vulnerable patient populations – at a significantly reduced price, on average 59% below list price.[1]

Manufacturers may not charge more than the 340B ceiling price to a CE regardless of whether the CE purchases the drugs through a wholesaler or directly through the manufacturers.

74%

of small rural 340B hospitals rely on 340B savings to remain open.[2]

89%

of large urban 340B hospitals improve patient medication adherence with 340B savings.[2]

What are CEs?[3]

Hospitals	Non-hospital CEs
Must be either owned or operated by the state or local government; be a public or private nonprofit that has been granted government powers by the state or local government; or a private nonprofit organization that has a state or local government contract to provide care to low-income patients who don't qualify for Medicaid or Medicare	Are eligible based on receiving federal funding from the Health Resources & Services Administration (HRSA), Centers for Disease Control and Prevention (CDC), HHS' Office of Population Affairs, and the Indian Health Service
Examples include: • Disproportionate share hospitals (DSH) • Children's hospitals and cancer hospitals exempt from the Medicare prospective payment system • Sole community hospitals • Rural referral centers • Critical access hospitals	**Examples include:** • Federally qualified health centers (FQHC) • FQHC "look-alikes" • State-operated AIDS drugs assistance programs • Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs • Tuberculosis clinics • Black lung clinics • Title X family planning clinics • Sexually transmitted disease clinics • Hemophilia treatment centers • Tribal/urban Indian health centers • Native Hawaiian health centers

[1] Pharmaceutical Research and Manufacturers of America. September 2022.

[2] 340B Health. "2019 340B Health Annual Survey."

[3] Health Resources & Services Administration

CEs that participate in the 340B program typically save 25-50% on outpatient prescription drugs, clinic-administered drugs, and over-the-counter (OTC) drugs that are accompanied by a prescription, and in some cases, CEs can acquire drugs that are penny priced. With these cost savings, providers can reduce prices for patients, expand their services, treat more patients, and ultimately, improve overall patient care.

What are contract pharmacies (CPs)?

CEs may choose to contract with pharmacies to dispense 340B drugs to patients. Doing so enables the CE to reduce costs associated with having an in-house pharmacy, as well as broaden access to patients through additional locations and extended hours. Prior to dispensing drugs on the CE's behalf, the contract pharmacy (CP) must register for the 340B program. However, the CE remains responsible for ensuring all 340B program requirements are met and that diversion and duplicate discounts are prevented.

Initially, only a minority of CEs leveraged CPs to fill scripts and purchase inventory, but in recent years, more pharmacies have entered the 340B landscape as more CEs have started leveraging CPs to serve their patients. In fact, 50% of the U.S. pharmacy industry now serves as CPs for more than 8,000 CEs – two-thirds of which are large national retail chains, such as Walgreens, CVS, Walmart, and Kroger. These 30,000 pharmacy locations have more than 140,000 contractual relationships with 340B hospitals and other providers, meaning that multiple CPs are filling scripts for multiple CEs. Reconciling who is using what product for what facility under what price creates a process nightmare.

Manufacturers are managing these many-to-many relationships and are struggling to track who is buying what for whom and when. And unless CPs are diligently keeping their 340B and retail inventories separate, scripts could be filled with pharmaceuticals that were incorrectly discounted. As a result, there is a lot of potential for fraud and revenue leakage. Additionally, by inadvertently extending a 340B price to the retail arm of the CP, manufacturers can face government pricing implications that ultimately increase liabilities on Medicaid or other programs and put themselves at risk for fines and penalties for misrepresentation.

4,228%

increase in CP participation in 10 years (April 2010 to April 2020)[4]

24%

increase in the number of CP contractual relationships since 2020[5]

[4] BRG. "For-Profit Pharmacy Participation in the 340B Program." October 2020.

[5] Drug Channels. "Exclusive: 340B Continues Its Unbridled Takeover of Pharmacies and PBMs." June 15, 2021.

Recently, manufacturers have begun to take a stand and demand a more streamlined, one-channel process. Many manufacturers are requiring CEs' CPs to submit 340B claims data to help them identify duplicate discounts and ineligible claims, and others have taken steps to limit the number of CPs to one per CE. While it's too early to say how these moves could shake out in the long term, it's clear the process has become too complex and too risky to continue as is.

Growth of the 340B program is skyrocketing.

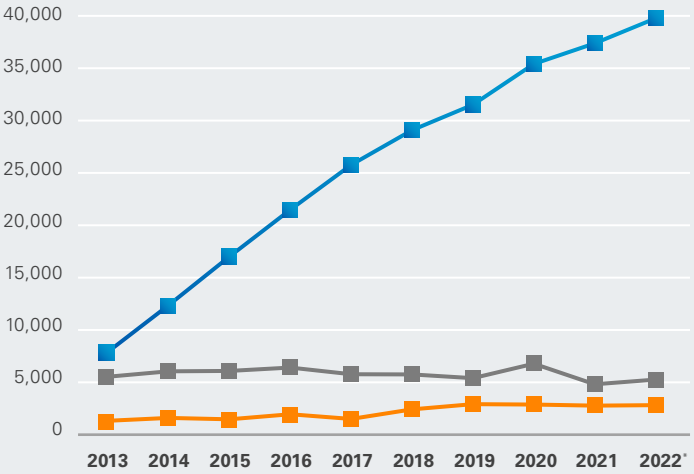
Based on data from HRSA, 340B drug purchases equated to $43.9 billion in 2021 – a 15.6% increase from 2020.[6] That amounts to approximately 14% of the U.S. drug market.[7]

Every year, thousands of new CEs and CPs enter or leave the 340B program, making it critical that manufacturers have a clean line of sight into eligibility and CE-CP relationships.

15.6%

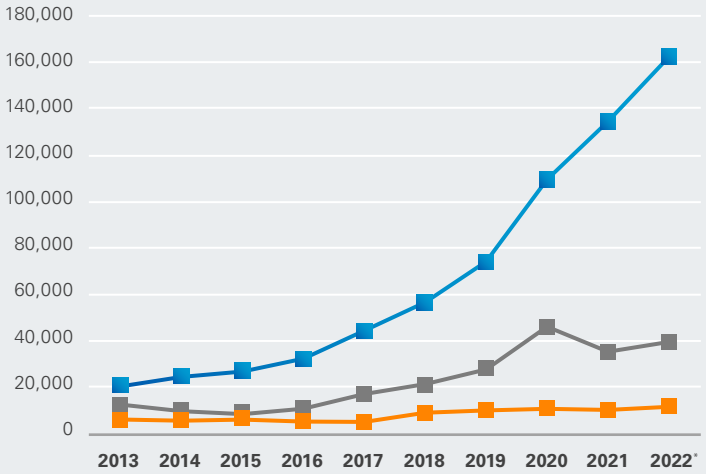
increase in 340B drug purchases from 2020 to 2021

CE activity 2013 to 2022[8]



*2022 through 10/31/2022

CP activity 2013 to 2022[8]



*2022 through 10/31/2022

[6] Drug Channels. "The 340B Program Climbed to $44 Billion in 2021–With Hospitals Grabbing Most of the Money." August 15, 2022.

[7] IQVIA. "340B Program Continues to Grow While Contract Pharmacy Restrictions Take Effect." April 5, 2022

[8] Based on data from HRSA Office of Pharmacy Affairs 340B OPAIS as of October 31, 2022.

Challenges with 340B

Civil Monetary Penalties Final Rule

In January 2019, the 340B CMP Final Rule went into effect. If a manufacturer knowingly and intentionally charges a CE more than the drug's ceiling price – even if the overcharge is a wholesaler's error – they are subject to a CMP in addition to being obligated to refund the CE the overcharge.

According to HRSA, overcharging may occur at the time of the original sale or when the ceiling price is recalculated.[9] Manufacturers are expected to resolve any overpayments and notify HRSA of their intent to issue a refund. Failure to do so will result in CMPs.

Dispersing these refunds can be challenging. Not only can it be difficult to calculate the exact refund amount for the overcharge, but processing the refund can be complicated as well. Without correct data on qualified CEs, manufacturers may be refunding money to entities that are not entitled to 340B pricing. They must know whether to process the rebate through a third-party company or directly to the CE. And they must make sure the payment is actually received.

In other words, there's much more to compliance than "calculate and cut." Manufacturers need an efficient rebating process, complete visibility into their distribution network, and real-time tracking and reporting.

Duplicate Discount Prohibition

Manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. CEs are responsible for determining whether they will use 340B drugs for Medicaid patients (i.e., carve in) or purchase Medicaid-covered outpatient drugs outside the 340B program (i.e., carve out). If the latter, Medicaid billing rules would apply. CEs are required to list the Medicaid states in which they will carve in, upon enrollment in the 340B program.

CEs should be maintaining their 340B priced inventory separately from non-340B priced inventory. While this can be done using a physical or a virtual separation process, popularity of a virtual approach has increased substantially. However, as CEs have broadened their CP networks, they lose visibility into how that inventory is utilized.

[9] Federal Register. "340B Drug Pricing Program."

As a result, the manufacturer may receive a rebate claim for a product that was acquired at a 340B price and dispensed to a patient served by a commercial insurance plan, Medicaid, or other government healthcare program.

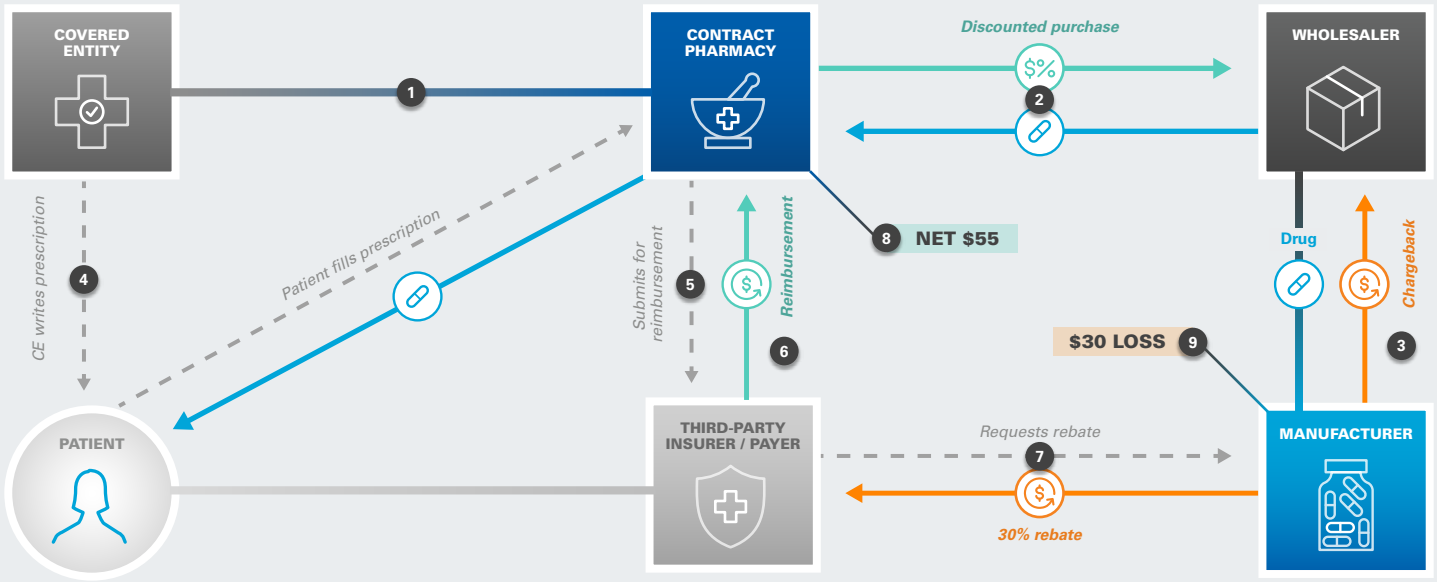
In this case, the drug was purchased at the discounted 340B price and now a third-party insurer has submitted a prescription utilization line. These duplicate discounts – known as double or even triple dipping – can result in significant revenue loss for the manufacturer.

CEs are prohibited from seeking Medicaid reimbursement for prescriptions dispensed using 340B priced products. However, manufacturers often carry the biggest burden of trying to validate rebate claims data and detailed data on 340B drug purchases, especially when they pertain to commercial insurances.

Double or triple dipping results in significant revenue loss

Figure 1

What causes a duplicate discount?



1. CE participates in 340B program and engages with a CP.
2. CP purchases drug from a wholesaler at the 340B price of $50 (a 50% discount off the $100 list price).
3. Manufacturer pays a chargeback to the wholesaler for the difference of $50.
4. A patient gets a prescription from a doctor at a CE. The patient fills the prescription at the CP, showing their card for third-party insurance.
5. The CP submits the prescription to the third-party payer for reimbursement.
6. The payer, which has contracted with the manufacturer to receive a rebate, reimburses the pharmacy $105.
7. The payer requests and receives a 30% rebate from the manufacturer.
8. The CP made $55 on the transaction.
9. The manufacturer paid multiple discounts on the same product – 50% upfront discount for the 340B price and 30% rebate to the insurer – resulting in $30 of revenue leakage.

For example, say a CE purchases a $100 drug for $50 (or a 50% 340B discount). The drug is then dispensed to a patient who has commercial insurance. The third-party payer receives a claim in which it reimburses $105; through a contract with this payer, the manufacturer has agreed to pay a rebate. The CE made $55 on the transaction. This isn't illegal, as gaps in regulations permit this for the commercially insured. Ultimately, this means the manufacturer has paid multiple discounts on the same product – a 50% upfront discount for the 340B price and then another rebate to the insurer. This form of revenue leakage becomes even more pronounced if the 340B was "penny priced" – as the manufacturer could end up paying more discounts than the price of the product.

While manufacturers aren't opposed to paying a 340B discount, they do not want to pay more than one discount on the same prescription. Unfortunately, it's not a question of "if" this will happen; it's a question of "how much." To avoid these issues, manufacturers need a direct line of sight, as well as access to real-time data, so they can definitively determine whether a prescription was dispensed from 340B inventory. This would allow them to review claim-level data for duplicates and gain visibility into purchasing patterns.

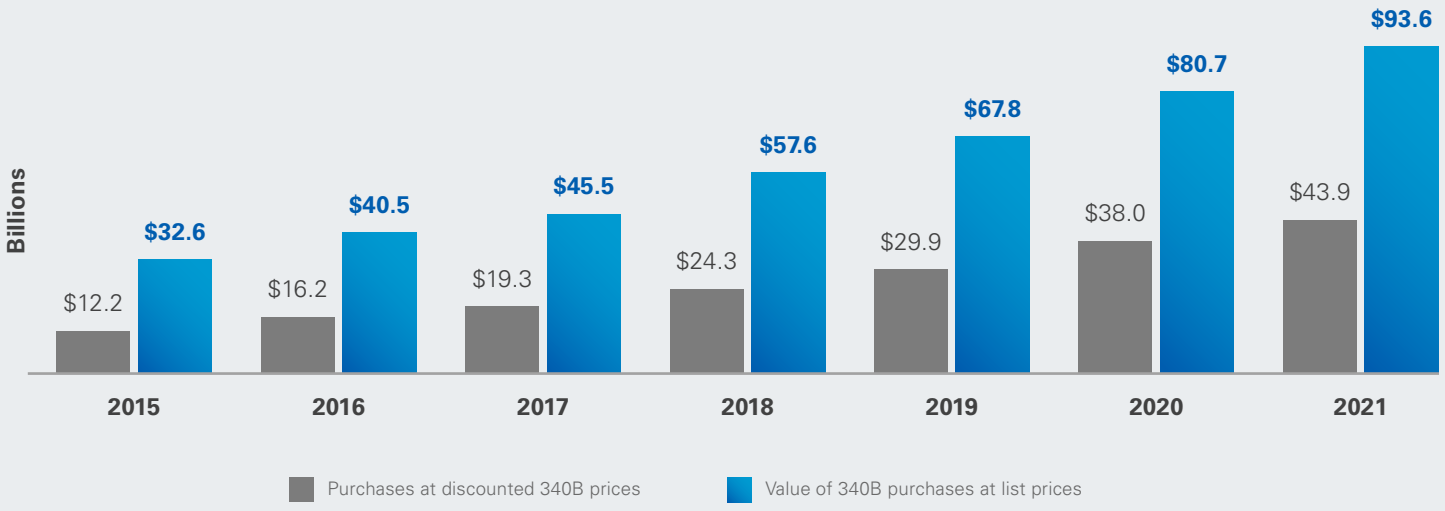
429

out of

1,240

In 1,240 audits performed between 2012 and 2019, HRSA found 429 instances of duplicate discounts[10]

340B drug pricing program, purchases by covered entities[11]



[10] PhRMA. "Key takeaways from new GAO report on covered entities' lack of compliance with 340B requirements." December 15, 2020.

[11] Drug Channels. "The 340B Program Climbed to $44 Billion in 2021–With Hospitals Grabbing Most of the Money." August 15, 2022.

Calculating 340B pricing

Ensuring that each CE is charged the correct price on every transaction is difficult and requires advanced systems capabilities. The 340B price is calculated from other related price calculations including AMP, best price (BP), and the Medicaid unit rebate amount (URA). If one of these calculations is incorrect, then the 340B price is by definition wrong.

340B price = quarterly AMP – federal URA		
For non-innovator products	For innovator products	
Federal URA (N) = quarterly AMP x Medicaid rebate % + CPIU inflation rebate	Federal URA (S,I) = max (quarterly AMP – BP, Medicaid Rebate % x quarterly AMP) + CPIU inflation rebate	
Medicaid rebate percentage varies according to product type:		
23.1% Innovators (S,I)	**13%** Non-innovator (N)	**17.1%** Exclusive pediatric and clotting factors
CPIU inflation rebate = current AMP – (base AMP x inflation) Including inflation on non-innovator drugs started in 2017.		

The definition of "best price" has been revised over the years, most notably with the Deficit Reduction Act, and while it is better defined in contrast to the AMP rules, the initial BP manufacturers file with CMS is often calculated probabilistically due to lagged transactions and discounts such as rebates and fees. This means that even if the manufacturer's processes and systems work perfectly, eventual restatements of some BP calculations are unavoidable.

Monthly and quarterly AMP calculations are more straightforward from a timing perspective because lagged discounts are smoothed and weighted over a rolling 12-month period. As such, AMP is not normally restated retroactively unless a major calculation error has been uncovered. Additionally, many of the largest lagged discount categories (e.g., PBM rebates, returns) are now excluded from AMP.

Since manufacturers are now required to remedy overcharges, but cannot absorb or net out undercharges, they are caught in a "Catch-22." If BP is too low, then the supplier is losing margin due to excessively low prices and potentially increased Medicaid rebate liability. If BP is too high, then in the best case the supplier owes refunds to every CE invoiced at the pre-restatement price. In the worst case, they may be exposed to civil or criminal penalties if HRSA considers it "intentional" overcharging.

Once again, the criticality of internal controls and automated processes and systems for commercial and government pricing cannot be overstated; however, robust standard operating procedures and policy documentation alone are insufficient. As such, predicting BP accurately is now more critical than ever.

Model N provides BP and best price initial calculation support based on actual data. Manufacturers can fully automate the various approaches to best price initial (best possible price, best priced accrued, and best priced forecast), as well as leverage ad-hoc analysis, trending, and visualization to underlying transactions and calculation data to support decision-making.

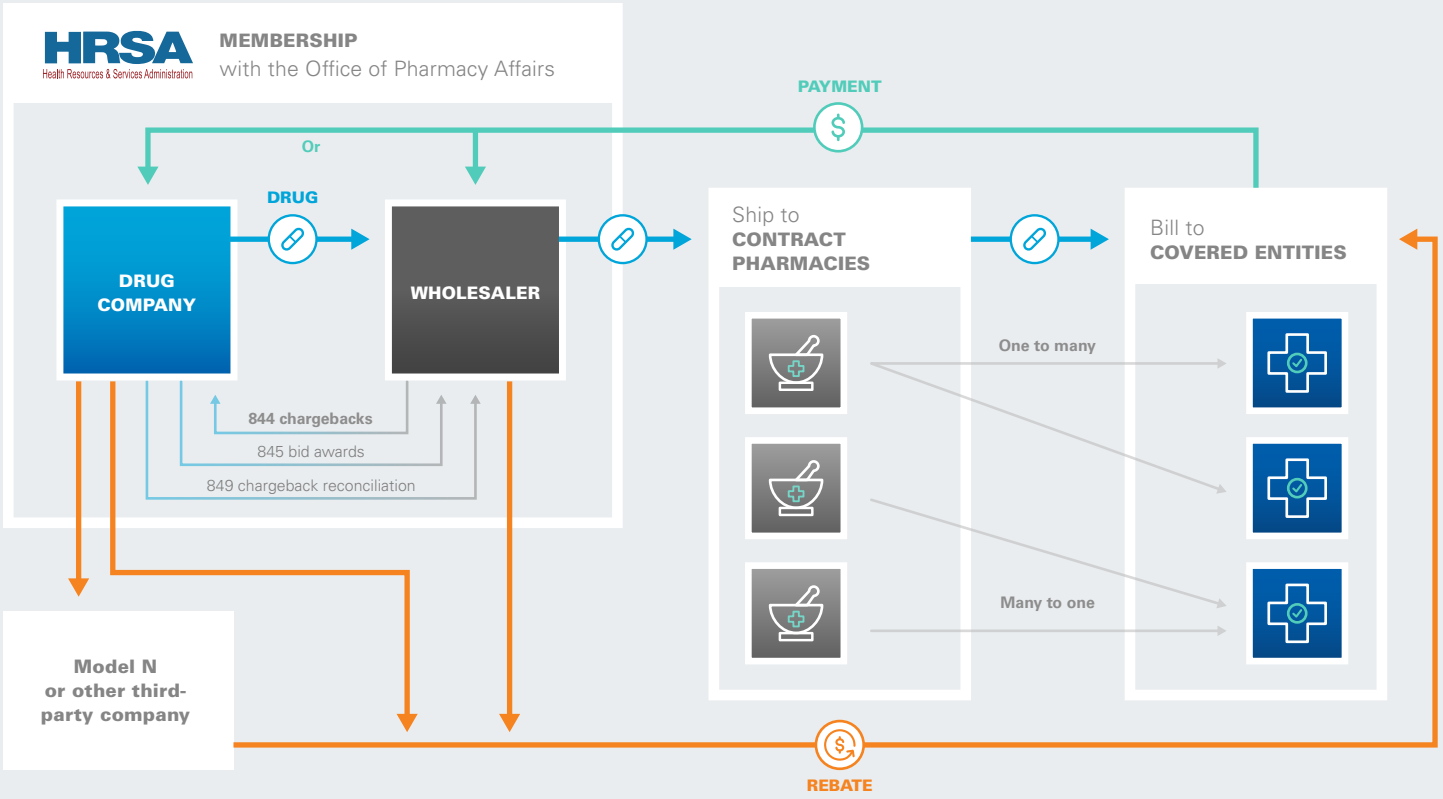
Processing 340B chargebacks

With the growth of the 340B program and the addition of new CEs, the volume of chargeback transactions is skyrocketing.

Maintaining account information about CEs is a critical task for any manufacturer or distributor. To ensure they provide the right pricing and adhere to 340B regulations, manufacturers need a single system of record that can provide visibility into CEs' eligibility, as well as manage the identifiers for CEs and associated CPs for chargeback processing.

As indicated in *Figure 2*, the process for managing chargeback submission and reconciliation is similar to the commercial process associated with group purchasing organizations (GPOs) and integrated delivery networks (IDNs).

Figure 2 **The process for managing 340B chargeback submission and reconciliation**



Drug company	Wholesaler	Covered entity
• Updates 340B eligibility (OPA database) • Calculates and publishes AMP, BP, URA, and 340B pricelists • Notifies wholesalers of 340B prices (845 bid award)	• Processes order and shipment • Verifies covered entity and contract pharmacy eligibility • Claims and reconciles 340B chargeback with manufacturer	**Entitled to a refund if:** • Incorrectly invoiced • 340B price is restated downward by manufacturer retroactively

Likely, eligibility information is extracted from the Office of Pharmacy Affairs (OPA) database on a monthly or quarterly basis. This information is then loaded into a manufacturer's internal systems. At the end of the quarter, they must perform AMP, BP, URA, and 340B price calculations.

Manufacturers are responsible for communicating their 340B quarterly pricing to wholesalers and distributors. Pricing can be communicated via EDI using an 845 transaction. If there is a delay or breakdown in the pricing update, the seller may not invoice the CE at the correct price.

To improve the chargeback process, follow these best practices.

Always reverify eligibility before honoring a chargeback request by leveraging OPA IDs to identify CEs and CPs when a 340B chargeback is submitted.

Use the bill-to and ship-to fields in EDI mapping. During chargeback reconciliation, identify the appropriate billable entity (CE) and reconcile the correct price.

Make chargeback information available for validations in other processes (e.g., managed care script scrubbing).

Generating an audit trail

Manufacturers participating in the 340B program are subject to audits by HRSA to ensure compliance. Unlike CEs that must be recertified annually, manufacturers are not subject to recertification. However, manufacturers are penalized – through fines and reputational damage – for violating 340B program requirements.

To support internal and external audits, Model N helps manufacturers gather the right information from the application, prepare a timely and accurate list of CEs, track contracts, and calculate pricing. In addition, the Model N platform helps track 340B IDs, cross-reference IDs, identify program start and end dates, and handle retroactive 340B eligibility. This capability is important as it helps facilitate the reversal of chargebacks to any CEs that lost eligibility and were erroneously paid at the 340B price.

With complete transparency into contracting, pricing, rebating, and chargebacks, manufacturers can ensure traceability, reproduceable processes, and accurate audit trails.

Ensuring compliance with 340B requirements

Per their PPA, manufacturers are required to refund charges to CEs that exceed the 340B ceiling price. If a manufacturer knowingly or intentionally overcharges a CE for 340B drugs, HRSA can impose civil monetary penalties in addition to the refunds. Noncompliance can also result in the termination of the manufacturer's PPA, which would then exclude their drugs from Medicaid and Medicare Part B coverage.

Depending on the timeframe between when a manufacturer identifies that a refund is necessary and when it is calculated and paid – as well as whether the amounts involved are material – the manufacturer may need to perform accruals. For any SOX compliance issues involving liability, calculations, disbursing funds, or crediting accounts, manufacturers should ensure they have the appropriate oversight and accountability in place so that they can pass SOX audits.

Accurate accruals are crucial to reducing overall revenue leakage. Under the 340B regulations, if a manufacturer undercharges a CE, they cannot go back to the CE and charge more later. On the other hand, if the CE is overcharged, the manufacturer is required to return the excess.

Reduce revenue leakage with accurate accruals

Model N can calculate the 340B refund utilizing the rebate functionality within Model N Provider Management. Additionally, Model N offers an Expert Service that helps manufacturers analyze system data to determine the 340B refunds for which they're liable.

Improve your processes and optimize revenue

Model N can help manufacturers efficiently manage their 340B and revenue management processes, so they can rapidly adjust to changes and mitigate risk. With Model N's intelligent platform that combines technology, data and analytics, and expert services, they can better manage relationships between CEs and CPs and gain insight and control over 340B discounts.

Model N Provider Management

- Store all identifiers for CEs and CPs including 340B ID, HIN, DEA, and trading partner-specific identifiers.
- Create and maintain PHSA ceiling and sub-ceiling contracts including dynamic price changes published as a result of government pricing calculations.
- Automatically trigger wholesaler notifications of 340B IDs and contract eligibility changes.
- Generate rebate payments for 340B price restatements.

Model N Medicaid

- Leverage a flexible formula builder to support changes in URA calculations.
- Process timely and accurate payments for federal, state, and supplemental programs.
- Automate validations to identify outliers in any claims.

Model N Government Pricing

- Automate workflow processing to ensure that AMP, BP, and URA have been approved before 340B is published.
- Forecast best price possible, best price actual, best price forecast.
- Efficiently manage monthly and quarterly government price reporting requirements.
- Align commercial and government price management.

Validata

- Perform up to 56 script-level validations on incoming line items.
- Reduce errors in processing data, preventing overpayments and administrative fees.
- Stay current with NCPDP standards for claim detail and reconciliation formats.
- Address the duplicate discount problem with the 340B add-on software.

Let Model N help you conquer your challenges with 340B.
Schedule a demo at modeln.com to see our solution in action.

SCHEDULE A DEMO