Best Practices for Managing PHS 340B Chargebacks

Staying Compliant to Health Care Reform Mandates with Limited Guidance

A Model N White Paper
Introduction

The Patient Protection and Affordable Care Act of 2010 (collectively “ACA”) has had sweeping ramifications for the health care pricing and reimbursement landscape, impacting providers, payers, manufacturers, pharmacies, and consumers. The ACA has deeply altered the Medicaid Drug Program including but, not limited to redefining Average Manufacturer Price, Federal Upper Limits, and the rebate payment rates manufacturers pay to the States.

ACA also substantially modified the Public Health Service (PHS) 340B Drug Pricing Program. First, it substantially expanded the definition of Covered Entities (CE) so that many more providers can purchase drugs at the 340B price (effectively equivalent to the Medicaid price); a trend public health care policy advocates want to expand. Second, new program integrity provisions require manufacturers to address overcharging program participants. The result of both changes is the volume of 340B chargeback transactions is growing, and the financial and legal implications of price errors are becoming more hazardous.

This paper will focus on operational and systems best practices and practical approaches for managing uncertainty and 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).

Growth of the 340B Program

According to the September 2011 report issued by the Congressional Government Accountability Office (GAO), the 340B Program accounts for an estimated $6B in pharmaceutical purchases annually. Surprisingly, GAO estimates that 33% or more of all US hospitals and network affiliates are now eligible for 340B pricing as the number of covered entities (CE) has more than doubled in the last ten years to more than 16,000.

Model N’s analysis of the Office of Pharmacy Affairs database indicates there have been 2,378 new CEs and 550 terminations in just the last six quarters (i.e., Q4-2010 to Q1-2012) alone (see Figure 1 below). Maintaining account information about Covered Entities is a critical task for any supplier and distributor supporting the PHS program. Government programs now make up almost 50% of the domestic drug market. While GP and other regulatory solutions can ensure timely and accurate reporting and claims processing that minimize the risk of noncompliance to government mandates, the total effectiveness of such systems is inextricably linked to the commercial Revenue Management processes a manufacturer puts in place.

Figure 1: New and Expired Contract Pharmacies

![Covered Entities (CE)](image-url)
Over the same period, Model N’s analysis shows an even greater number of changes to Contract Pharmacies (CP) that service Covered Entities. Figure 2 below shows 4,417 new CPs added but only 753 expirations.

![Figure 2: New and Expired Contract Pharmacies](image)

Manufacturers that sell indirect only through wholesalers and distributors may not need to build full customer master records for Contract Pharmacy, whereas direct sellers or drop-shippers that verify CP eligibility before transacting should maintain complete account information.

Nevertheless manufacturers will minimally need to manage the identifiers for CEs and their associated CPs for chargeback processing.¹

Unfortunately, the OPA database does not report a unique number like a DEA or HIN for Contract Pharmacies. Complicating matters, Covered Entities often have several Contract Pharmacies servicing them. In such cases the accepted practice is to identify CPs using the Base HIN associated with the Covered Entity (i.e., The first seven digits), and assign a unique HIN suffix to represent each CP (i.e., Positions 8 and 9 on the HIN number). 340B ID maintenance and usage is discussed in greater detail in Section 3.

¹ Since the proposed AMP rule redefines eligibility, Retail Community Pharmacy and the pending change to “presumed inclusion”, manufacturers may want to consider full account maintenance for Contract Pharmacies and properly treat categorize transactions, particularly at multi-use pharmacies.
Overview of 340B Chargebacks

In many ways, the process for managing 340B chargeback submission and reconciliation is identical to the commercial process associated with GPO or IDN contracts with some notable exceptions (see Figure 3).

Figure 3: 340B Chargeback Process

Generally both Manufacturers and Wholesalers will extract program eligibility information from the Office of Pharmacy Affairs (OPA) database on a monthly or quarterly basis, which is loaded into their internal systems. After a quarter ends, Manufacturers will perform their government price calculations of Average Manufacturer Price (AMP), Best Price (BP), Unit Rebate Amount, and 340B prices. Section 5.2 provides more detail how the 340B Ceiling Price is derived from AMP, BP and URA.

Manufacturers are responsible for communicating their quarterly 340B pricing to wholesalers and distributors. For the more technology savvy trading partners, pricing is communicated via EDI using an 845 transaction. If there is a delay or breakdown in the process, then the seller may not invoice the CE at the correct price.

Prior to shipping a drug to a Covered Entity or to their designated Contract Pharmacy, Wholesalers should verify eligibility against the OPA database. At the January 2012 ACI Chargeback and Rebate conference, John Shakow of King and Spalding LLC reminded attendees Covered Entities are not technically eligible until they have been added to the OPA database with a valid 340B ID, irrespective of any other paperwork to the contrary. While most wholesalers perform this check before transacting, to be safe manufacturers should not assume that it was done correctly on each and every 340B purchase, and since the liability is on the manufacturer, they should re-verify eligibility before honoring a chargeback request.

Note that all of the following terms including 340B Price, PHS Ceiling, PHS Base Price, 340B Ceiling, Section 602 Ceiling, Section 256b Ceiling all mean the same thing (Source: John Shakow, King and Spalding LLC).
In the commercial contract marketplace, prices are negotiated directly between the parties. Unlike the 340B program, contract prices are not mathematically derived from statutory price calculations, which themselves are comprised of thousands or millions of sales and rebate transactions. If a price is incorrect, a commercial customer can be easily credited/re-billed, or otherwise made whole. This is not the case with the 340B program. Section 5 will address ACA 7102 (a) and the myriad of open questions relative to overcharging covered entities, as well as the underlying Government Price calculations that are used to derive quarterly 340B pricing.

**Best Practices for Managing 340B Eligibility**

Confronted with 500 to 1,000 OPA database changes per quarter, Contract and Chargeback departments are straining to keep up. Typically there are three approaches to keeping membership and eligibility up to date for any type of contract, and the PHS program is no different from a process perspective. Table 1 describes the advantages and disadvantages of each approach.

<table>
<thead>
<tr>
<th>Membership</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Proactive</strong></td>
<td>Some manufacturers will extract from the OPA database every month or quarter and proactively create missing customers and assign 340B IDs for every new Covered Entity. This approach has multiple benefits from a compliance perspective and it also enables manufacturers the ability to transmit 340B IDs on EDI documents (i.e., 844, 845 and 849) with wholesalers. The downside is the additional work to maintain customer records that may never purchase products.</td>
</tr>
<tr>
<td><strong>Reactive</strong></td>
<td>Some manufacturers verify 340B eligibility and contract number at the time chargeback transactions are processed. If the transaction is invalid, then the manufacturers will add the valid 340B records to their system and reprocess the chargeback line. While this approach requires less up-front effort, it squarely puts the onus and risk of 340B verification exclusively on the chargeback processing application. Many systems have sophisticated controls to prevent invalid 340B sales; however they should be tested vigorously.</td>
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<tr>
<td><strong>Hybrid</strong></td>
<td>This approach balances both the proactive and reactive methods. The idea to proactively load covered entity types that are more apt to purchase your products, but reactively address chargeback rejections for covered entity types that are unlikely to, or rarely purchase your products. For example, if you don’t market oral contraceptives, there is probably no reason to proactively load Family Planning Clinics in advance of sales transactions. On the other hand if you sell oncology products then you would probably want to proactively load freestanding cancer centers. The hybrid approach offers a risk adjusted approach for companies with resource constraints.</td>
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**340B FAQ**

**What are the top 1-2 implications from a finance/accounting perspective that I need to worry about relative to the 340B refund process?**

Although there are many implications that could be top of mind depending on individual circumstances, two that stand out are accruals and SOX compliance. Depending on the time frame between when you know a refund is necessary and when you calculate and pay it — as well as whether the amounts involved are material — you might need to accrue for the refund. For any SOX compliance issues involving liability, calculations, disbursing funds, or crediting accounts, you want to make sure you have the appropriate oversight and accountability in place so that you can pass SOX audits.
Information technology can reduce the manual effort by capturing, mapping, and loading data in an automated fashion. Most vendors have some sort of customer ID cross reference and flexible file import mapping tool. Often these tools work very well for program changes and expirations. On the other hand automation alone is less reliable when it comes to creating new customer records, assigning classes of trade (COT), and cross referencing the variety of alternate identifiers like HIN, DEA, and GLN to 340B ID. Nonetheless software solutions can provide partial automation.

Lastly, be sure that your system can keep historical audit trails on 340B IDs, cross reference IDs, and program start and end dates at a bare minimum. Your system should also be able to handle retroactive (or “backdated”) 340B eligibility. If it is determined that a CE lost its eligibility sometime in the past, this will help facilitate reversing any chargebacks erroneously paid at the 340B price. Additionally your system should be able to manage price eligibility directly from the start and end date as opposed to the creation of a pseudo-Class of Trade.

**EDI Using 340B ID**

Today the majority of EDI communications of chargeback information related to the 340B program is communicated using HIN numbers to determine the Covered Entity and Contract Pharmacy. While the HIN number is a more stable identifier than DEA License Number, and more universally recognized than GLN, its original design was to enumerate ‘bricks and mortar’ locations. As described above, HIN can be and is used to model CEs, CPs, and even multi-use CPs.

On most chargeback submissions in the industry, wholesalers and manufacturers usually exchange either the DEA or HIN of the “Ship To” customer and with good reason. Understanding the class of trade and the contract compliance of the end customer is essential to accurate government price calculations and class of trade eligibility. However when it comes to 340B chargebacks, it is critical to transmit the 340B ID of the “Bill To” (or “Sold To”) instead of or in addition to the Ship To identifier due to the proliferation of contract pharmacies. The Ship To information will be relevant to the contract pharmacy and the Sold To information will represent the covered entity.

Figure 4 indicates the status of and usage of 340B ID in the three main EDI documents used for chargeback processing among the Big Three Drug Wholesalers. Note that both Cardinal and McKesson also require a HIN identifier for the Contract Pharmacy in addition to the 340B ID of the Covered Entity. By sending both identifiers, both manufacturers and wholesalers can validate the eligibility of the Covered Entity, the Contract Pharmacy, and the relationship between both parties to a greater degree of precision and confidence.

**340B FAQ**

*Regarding Medicaid restatements, BP true-ups, and the retroactive PHS price impact, how can you mitigate the amount of identified Medicaid restatements resulting from data or methodology error?*

Acquiring the most accurate best price right off the bat will really minimize the number of BP restatement, and therefore the number of URA restatements. Often manufacturers follow a policy of initially filing the lowest “attainable” price and restating, as a practice, several quarters later with the actual attained BP.

Something to consider is to use historical purchasing patterns to predict and forecast future best price. Often in these cases, your BP could be accurate as of the initial filing — thus reducing BP and PHS restatement.
Figure 4: Status of 340B in EDI by Big 3 Wholesalers as January 2012

<table>
<thead>
<tr>
<th>Wholesaler</th>
<th>Accept on 845</th>
<th>Send on 844</th>
<th>Accept on 849</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmerisourceBergen</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>1 Must send HIN and 340b ID. HIN must be first. 2 Send 340b ID in N1 or REF segment 3 Should place 340b ID in N1 or REF segment based on how 844 is sent.</td>
</tr>
<tr>
<td>Cardinal Health</td>
<td>Yes ¹</td>
<td>Yes ²</td>
<td>Yes ³</td>
<td></td>
</tr>
<tr>
<td>McKesson</td>
<td>Yes ⁵</td>
<td>Yes ⁵</td>
<td>Yes ⁵</td>
<td>³ See comments for Cardinal Health</td>
</tr>
</tbody>
</table>

Model N will collect information on regional wholesalers and specialty distributors for publication at a later date.

**Practical Guidelines for Managing 340B Overcharges**

**HRSA Instructed by Congress to Provide Procedures**

Section 7102 (a) of the ACA introduced specific language to address known and unknowing overcharges of a covered entity. Specifically ACA states “The Secretary is also tasked with establishing procedures for the refund of overcharges, including overcharges resulting from discounts or rebates issued by manufactures after the sale of drugs to the covered entity that have the effect of lowering the ceiling price.”

Whenever new regulations are enacted, there is inevitably a period of legal and operational uncertainty, especially when the rules impact markets as vital and multifaceted as the US healthcare system. In such cases, the generally accepted practice is to interpret the regulations in the spirit the statute in consultation with legal and compliance experts. By documenting open questions and working assumptions, manufacturers demonstrate their intent to fully comply with the law, while waiting regulatory guidance, or in this case “procedures.”
Table 2 below provides a partial list of critical operational and financial questions that manufacturers should evaluate carefully with appropriate legal representation. Many of the questions listed below are relevant for drug manufacturers negotiating an agreement with a third party such as Apexus to provide refunds.

**Table 1: Partial List of Questions on Overcharges**

- The statute only mentions remedy for overcharges, but can I net undercharges when I process overcharges even though ACA does not specifically mention it?
- If I cannot bill for undercharges, can I continue to net undercharges if I’ve been voluntarily crediting overcharges prior to ACA?
- How long after I discover an overcharge do I have to issue a refund? Is there a time based penalty or interest owed?
- If the adjustment to 340B was the result of a BP, AMP or URA restatement, is there limitation on how long I have to restate my prices?
- What are the advantages and disadvantages of using Apexus vs. issuing refunds directly to the CE?
- If I sell direct, can I issue the refund as a credit against future purchases?
- Should I report 340B prices to HRSA even though no instructions have been provided to manufacturers yet?
- What do I specifically need to disclose to HRSA (formats, content, etc.)?
- Is there a materiality limit? What should I do if I owe $0.25 to 16,000 CEs?
- If I contract for Prime Vendor or Wholesalers to refund the covered entity am I still liable once funds are transferred to the intermediary?
- Can the Prime Vendor indemnify my company from a regulatory compliance perspective?
- What if the Covered Entity is no longer eligible or is closed?
- Are refunds assignable if the Covered Entity is sold or merges? Am I responsible for refunding the new owner?

**Government Price Considerations**

Ensuring that each and every Covered Entity is charged the correct price on every transaction is difficult and requires advanced systems capabilities. As industry practitioners know, the 340B price itself is calculated from other related price calculations including Average Manufacturer Price, Best Price and the Medicaid Unit Rebate Amount (see Figure 6). If anyone of these calculations is incorrect then the 340B price is by definition wrong.

Further complicating matters, the ACA itself has also impacted the Medicaid Rebate calculation and Average Manufacturer Price. In fact, the proposed rule for AMP has only reached the commentary period as of the time of this report\(^3\).

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\(^3\) The proposed rule for AMP was published at the time this briefing document was written. Model N will comment on AMP substantively outside of this report in separate communications.
Best Price has undergone revisions over the years, most notably with the Deficit Reduction Act, and while it is better defined in contrast to the proposed AMP rules, the initial Best Price 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 Best Price 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 twelve 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, etc.) are now excluded from AMP.

Since manufacturers are now required to remedy overcharges, but cannot absorb or net out undercharges\(^4\), 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 “intentional” overcharging.

Once again, the criticality of internal controls and automated processes and systems for commercial and government pricing cannot be overstated, however robust SOPs and policy documentation alone are insufficient. As such, Model N’s opinion is that predicting BP accurately is now more critical than ever.

**Advanced Forecasting of Best Price Initial**

Model N has observed various approaches to calculating Best Price Initial (BPI) at customers, but they largely fall into three categories:

- Best Price Possible (BPP)
- Best Price Accrued (BPA)
- Best Price Forecast (BPF)

1. Medicaid rebate % varies according to product type:
   - Innovators (S,I) = 23.1%
   - Exclusive Pediatric and Clotting Factors = 17.1%

2. CPIU inflation factor= Current AMP – (Base AMP* Inflation)

\[340B\text{ Price=} \text{Quarterly AMP}^* (1 – \text{Federal URA})\]

**For Non-Innovator Products:**

\[
\text{Federal URA (N)} = q\text{AMP} \times (1-13\%)
\]

**For Innovator Products:**

\[
\text{Federal URA (S,I)} = (\text{Max} (q\text{AMP} – \text{BP}, \text{Medicaid Rebate }%)^1 \times q\text{AMP}) + \text{CPIU Inflation Factor}^2
\]

1. Medicaid rebate % varies according to product type:
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2. CPIU inflation factor= Current AMP – (Base AMP* Inflation)

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\(^{\text{4}}\) See Section 7102(a)
**Best Price Possible (BPP)** considers all contracts, price points, sales, discounts and rebates from which the highest potential discounts or lowest prices are calculated assuming all performance incentives are earned. BPP is the most conservative approach from a compliance perspective because it calculates the lowest achievable commercial price and as a result the highest possible Medicaid rebate and lowest potential 340B price. On the other hand, if the assumption that all relevant incentives earned proves not to be the case and the true Best Price is higher, the manufacturer cannot re-bill for undercharges, which will lead to margin loss. The related implications on Medicaid rebates will not be addressed in this paper.

**Best Price Accrued (BPA)** is a different approach than BPP in that it uses all actual transaction data available at the quarter end to perform the Best Price calculation. However instead of using actual rebate data which is usually not available yet, it uses rebate and fee accrual data to fill in the blanks on lagged discounts. Thus, while BPA may be more accurate than BPP, it is also more manual because the rebate/fee accrual data is often massaged and loaded manually. Often manufacturers have to spend considerable time to verify that the accrual data is correct.

**Best Price Forecast (BPF)** is similar to BPA, however instead of using rebate accrual data, the GP system algorithmically projects lagged discounts, rebates, and fees based on historical sales and utilization data. While BPF offers higher accuracy and more automation, it is also the most difficult to implement from a systems perspective. All contract and price data must be loaded into a centralized repository along with cleansed historical sales and utilization data. Also for those offering bundled incentives, the BPF projections must be able to dynamically spread or allocate discounts.

In our opinion, Best Price Accrued (BPA) is preferable to Best Price Possible (BPP), but Best Price Forecast (BPF) is the best practice for filing the Best Price Initial. At the same time, BPF is probably the most complex, resource intensive and manual of the three techniques.

Model N has always provided Best Price Initial and Best Price calculation support based on actual data. With the more recent releases, manufacturers can more fully automate the various approaches to Best Price Initial including numerous improvements to all its Regulatory Compliance applications. Model N also offers an Advanced Reporting System which will provide access, ad-hoc analysis, trending and visualization to the underlying transactions and calculation data.

**Revenue Management Solution for 340B Program Management**

To sustain the broader 340B processing needs of drug manufacturers requires various integrated capabilities, including contract and price management, chargeback validation and reconciliation, differential price rebates, EDI communications, reporting, and ERP system integration. Moreover, since 340B processes are intrinsically related to AMP, BP, and URA calculations, a 340B solution is ideally built into the commercial contract platform or is tightly integrated with it.

### 340B FAQ

**How would you determine the true purchasing entity other than asking the wholesaler?**

One best practice is to work with wholesalers to ensure “sold to” or “bill to” customer identifier, preferably 340B, and other information such as name and address are sent on the chargeback line when the product was shipped to a contract pharmacy.

The “ship to” information is good information to also collect, but without an identifier that is associated to a covered entity, the line will not be as easily adjudicated.
Model N’s Revenue Management Enterprise system provides embedded support for 340B program management within the following applications (see Figure 5):

- **Contract and Price Management**
- **Chargebacks**
- **Purchase-Based Rebates**
- **Government Pricing**

![Figure 6: Model N Revenue Management Enterprise Suite](image)

Model N Revenue Management includes the following feature sets to support the 340B program:

**Model N Contracts and Pricing Management**

- Ability to store all identifiers for covered entities and contract pharmacy including 340B ID, HIN, DEA, and trading partner specific identifiers
- Standard dataflow importers of 340B accounts and/or 340B identifiers
- Ability to create and maintain PHS Ceiling and Sub-Ceiling Contracts including dynamic price changes published as a result of GP pricing calculations
- Automatic trigger wholesaler notifications 340B IDs and contract eligibility changes using providing the output for x.12 EDI 845 Bid Award documents or generating Bid Award reports for wholesalers unable to process the 845
Model N Government Pricing

- Calculation of 340B pricing within the Government Pricing system including automated workflow processing to ensure that AMP, BP, and URA have been approved before 340B can be published.
- Support for Best Price Possible, Best Price Actual, and Best Price Forecast.

Model N Settlement Applications – Purchased-based Rebates and Chargebacks

- Full support of HDMA validations to notify analysts of possible discrepancies in PHS chargebacks and research tools to help adjudicate those lines
- 340B Refund program that will calculate price differential rebates for all sales transactions impacted by a revised Ceiling Price
- Flexible options for refund processing:
  - Pay a price differential rebate directly to the Covered Entity
  - Pay a price differential rebate to the Prime Vendor
  - Initiates Chargeback Resubmission Processing via Wholesaler
  - An optional switch to net Undercharges from Overcharges
- Payment package workflow, reporting and review process

Conclusion

Staying compliant in the face of ambiguous regulations has been a constant source of uncertainty for the past two decades and will certainly continue into the future. Nevertheless, waiting for perfect clarity to crystallize before proactively reviewing policies, procedures, and systems is highly problematic.

We have seen many times in practice that companies that incrementally adjust their compliance programs and infrastructure are far more adroit at adjusting to changes and ambiguity than their peers. Companies that document calculation assumptions and implement methodology swiftly often experience a greater level of auditability and confidence in certifications.

Author: David Weiss, Senior Solutions Director, Model N