

TOP 3 REASONS YOUR AMP CHANGED

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Large variances in Average Manufacturer Price (AMP) values are a common source of inquiry for pharmaceutical manufacturers. Questions often arise when internal stakeholders are trying to understand an undesired rebate liability or a lower-than-expected 340b/PHS price after the fact. Questions can also arise when CMS reaches out to inquire about a significant AMP variance (which is occurring with greater frequency). In any case, it's important for all stakeholders to understand what causes an AMP value to change – for better or worse.

AMP is a critically important value for any pharmaceutical manufacturer participating in the Medicaid Drug Rebate Program (MDRP), as it drives a manufacturer's Medicaid Rebate liability and the amount received for each 340b/PHS sale. Depending on the specific drug, **large changes in your AMP value can mean significant changes in profitability.**

It is not unusual for AMP values to vary from month to month or quarter to quarter (especially for generic drugs, which can consistently experience monthly variances of 20-30% or higher). Having performed AMP calculations across brand and generic pharmaceutical manufacturers for over a decade, we can tell you the driving forces behind large AMP variances tend to consistently fall into one of three categories:

1. CHANGE IN BUSINESS MODEL OR SALES MIX

The most common reason leading to AMP variance is changes in your business model or sales mix – meaning the proportion of your sales going to different types of customers versus prior periods. Changes in sales mix from month to month tend to be the biggest driver behind AMP variances, specifically for generic drugs. The proportion of sales to wholesalers (purchasing at WAC) versus the proportion of sales to other direct customers (purchasing at discounted pricing) can have a large impact on AMP values. As wholesalers place stocking orders at WAC, the result is often a large increase in gross direct sales for that specific drug in a given month (which typically leads to a large increase in AMP value). On the contrary, if a big-box store is purchasing 80% of your monthly volume at a significantly discounted price, versus only representing 20% of sales volume the prior month, you can expect a large decrease in AMP values.

Given the nature of marketing generic drugs to many different customers at many different price points, we typically expect to see month-over-month fluctuations based on the scenarios mentioned above. Brand drugs tend to see much more consistency in AMP values. There is less of a “sales mix” factor as pricing tends to be steadier across customers.

Like changes in sales mix, the addition or loss of a major contract or award can lead to a large AMP variance as well. While the sales mix tends to fluctuate month to month, gaining or losing contracts leads to a one-time and longer-lasting variance. For example, the addition of a major account award at a significantly discounted price will likely lead to a large uptick in sales volume, but since that volume is at a much lower price point, the AMP value will drop as a result and likely remain lower for the duration of that contract.

2. TIMING OF CHARGEBACK & REBATE PAYMENTS

The second most common factor leading to AMP changes is timing of chargeback and non-bona-fide rebate/credit processing and payments to a manufacturer's customers. A large increase in WAC sales to wholesalers will lead to an increase in AMP value, but as the wholesaler moves that product through various indirect customers, chargebacks and other rebates will likely follow. Once those additional discounts, in the form of chargebacks and rebates, flow through and are paid by the manufacturer, they are factored into the AMP calculation and will lead to a drop in AMP value. Many discounts lag and may not be applied until one, two, or even three or more months after the initial direct sale takes place.

Different types of rebates are paid on different cadences as well – monthly, quarterly, or annually – which can lead to large increases in discounts applied for a given month. Typically, when there are large increases in discounts, the AMP value will decrease as a result. However, the impact may not be as large as expected due to the “smoothing methodology” that is used in AMP calculations for applying chargeback and rebate dollars.

These discount values are applied in the calculation based on a rolling 12-month average. A “smoothing ratio” is calculated based upon the rolling 12-month average of chargeback or rebate dollars to the rolling 12-month average of eligible direct sales. That smoothing ratio is then applied to the current month’s eligible direct sales to determine the chargeback or rebate amount that is taken into consideration as a discount in the AMP calculation.

The reason this methodology is used (versus simply applying the exact dollar amount processed in a specific month) is to smooth out the impact of large variances in chargeback or rebate amounts processed. Although this methodology smooths out the impact and lessens the impact on AMP values, it is still one of the main drivers behind AMP variance. When smoothing ratios fluctuate over time, it changes the number of discounts applied which will cause the AMP value to increase or decrease as a result. This concept becomes significantly apparent when the price or customer mix was vastly different 10+ months ago. When those older months fall off the 12 month rolling averages, this can cause a major change in the ratio applied to the net eligible AMP sales.

In addition to typical discounts in the form of chargebacks and rebates, it is important to take into consideration any heavily discounted sales, such as short-dated sales. There’s a common, but inaccurate, assumption that short-dated (and similar) sales can be automatically excluded from AMP calculations. This is typically not true, and once those sales are factored in, the AMP calculation can take a significant dive. This can often lead to a lower-than-expected 340b/PHS price due to a couple of short-dated sales.

3. INCOMPLETE OR INACCURATE DATA

The third most common factor behind AMP variance is inaccurate, missing, or incomplete data sets. It is not uncommon for manufacturers to overlook or inadvertently forget to include certain data in their AMP calculations. For example, a quarter’s worth of customer rebate data gets accidentally left out of the calculation, only to be discovered several months later, resulting in an AMP restatement. Or pricing errors for many sales to a customer occur, resulting in a large credit and rebill effort to true-up the sales data.

These types of data inconsistencies are not uncommon and can lead to major changes in AMP values once they are properly accounted for. We tend to see more of these issues when a manufacturer relies on a system or “black box” to perform AMP calculations. Scenarios where data is simply fed into a system with little-to-no transparency can lead to significant risk of inaccurate or incomplete data going unnoticed for long periods of time. Once the issue is noticed, it typically requires recalculation of historical AMPs and often means unexpected changes in Medicaid rebates that were previously paid, as well as potential 340b/PHS refund efforts.

It is of utmost importance to ensure that complete and accurate data is always taken into consideration for all AMP calculations. If a system is performing the calcs with little-to-no human oversight, it is important to verify the data. If there is a questionable piece of data, an analyst performing a calculation can simply dig further and reach out to the appropriate parties for validation. If a system comes across a questionable piece of data, it likely will be taken into consideration in the AMP calculation – right or wrong – and may not be brought to anyone’s attention.

Having a basic understanding of what drives AMP values and what is behind AMP variance, whether it is expected or unexpected, will help manufacturers better prepare for changes in their Medicaid rebate liability and 340b/PHS pricing. If there is a need to move some short-dated product, expect an AMP decrease and drop in 340b pricing to follow. If wholesalers are placing large stocking orders, expect AMP to increase and potentially prepare for an increase in Medicaid rebates. When combined with prudent management, typical month-to-month variances tend to average out over the course of a quarter and shouldn’t result in major surprises. Additions or losses in major contracts, however, can have a lasting impact which could warrant adjustments to accruals.

Ensure you have a knowledgeable Government Pricing partner to help you understand your AMP value (including its [relationship to your baseline AMP](#)) and key changes so you can make the best-informed decisions to support your growth, profitability and compliance objectives.