Analyzing 340B and ASP interactions: Do Federal program rules disincentivize the use of VBCs, despite Medicaid Best Price reform?

This paper describes the interactions among Medicaid Best Price rebate calculations and those for 340B Ceiling Prices and Average Sales Prices which can create disincentives for providers and therapy developers from the use of Value-Based Contracts.

RESEARCH BRIEF

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BACKGROUND

The recently updated Medicaid Drug Rebate Program (MDRP) rule modifies calculation of Average Manufacturer Price (AMP) to improve the feasibility of value-based contracts (VBCs) for both commercial and Medicaid markets by excluding VBC commercial sales from the calculation of the Medicaid Best Price (MBP) rebate[1]. This change can also interact with the calculation of the 340B drug ceiling price and the Medicare Part B's Average Sales Price (ASP) when VBCs are employed.

The Medicaid Drug Rebate Program set rebates, not prices, that a developer must pay to a state Medicaid plan for each unit of the therapy used by its Medicaid beneficiaries. That rebate, in most cases, is the larger of either (i) the statutory rebate: 23.1% (17.1% for pediatric and clotting factors, 13% for Generics) of Average Manufacturer Price (the volume-weighted average price for all unit sales in a given quarter) or (ii) the 'best price' rebate: the difference between AMP and the lowest price paid by any commercial buyer[2]. The MDRP's best price reporting rules also now allow reporting "multiple best prices" when offering a value-based payment arrangement–one for each performance tier of the VBC.

Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to eligible health care organizations including community health centers, children's hospitals, hemophilia treatment centers, critical access hospitals (CAHs), sole community hospitals (SCHs), rural referral centers (RRCs), and public and nonprofit disproportionate share hospitals (DSH) that serve low-income and indigent populations. The program allows 340B organizations to stretch limited federal resources to reduce the price of outpatient pharmaceuticals for patients and expand health services to the patients and communities they serve.[3]

Key takeaways

VBCs impact the calculation of ASP (through the chain of AMP, MBP rebates, and 340B ceiling prices) in ways that may reduce provider margins on VBC products, discouraging the use of those products, of VBCs, or both.

Under the Multiple Best Prices option, product sales under a VBC are excluded from the calculation of AMP and so, VBC performance rebates will not impact the MBP rebate.

340B ceiling prices, which depend on the AMP, may be higher or lower after introducing VBCs depending on which payers engage in VBCs and product performance outcomes.

For rare therapies with VBCs, ASP volatility may occur that could trigger IRA Inflation Rebates.

ASP volatility may also affect provider margins for products whose reimbursement is based on ASP.

ASP reform to exclude VBC sales from ASP, as is done when calculating AMP, would mitigate the disincentives above.

ASP is the drug pricing method developed for drugs and biologicals covered under Medicare Part B. The Centers for Medicare & Medicaid (CMS) establishes ASP using a manufacturer's sales (net of discounts) to all purchasers of a drug in the U.S. in a calendar quarter divided by the total number of units of the drug sold by the manufacturer in the same quarter. Medicare Part B payment to providers is 106% of the ASP, less applicable beneficiary deductible and coinsurance.[4]

WHAT IS THE RELATIONSHIP BETWEEN MEDICAID BEST PRICE, ASP AND 340B?

FoCUS has mapped the interactions of VBCs with the MDRP (MBP) and 340B programs as well as with ASP to understand the incentives that payers, developers, and providers face when using a VBC.

Figure 1 illustrates the baseline connections (WITHOUT a VBC) of Medicaid Best Price rebate calculations to those for 340B ceiling prices and ASP. In this baseline, the AMP (the volume-weighted average of the reported bundled sales price for payer 1 and payer 2, each with 5 patients on therapy) is $450K and would result in a 23.1% mandatory rebate to Medicaid payers of $104K (red bar). Health Resources and Services Administration (HRSA), which administers the 340B program, would then calculate a 340B ceiling price of $346K by subtracting the MBP mandatory rebate amount from the AMP (left dark blue bar). This 340B ceiling price is the maximum amount that a 340B eligible entity can be charged for the product. That provider can then charge third party payers their standard, negotiated rates. For commercial payers this is often based on ASP and in this example the provider reimbursement is assumed to be ASP plus 6% or $477K. Providers would therefore earn at least a $131K margin ($477K commercial payer reimbursement minus the provider's $346K maximum ceiling price acquisition cost; right dark blue bar).

WHAT HAPPENS WHEN A VBC IS ADDED TO THE MEDICAID BEST PRICE, 340B, AND ASP PROCESS?

Based on the discount sales connections in Figure 1, the impact of a VBC is shown in Figure 2 when the VBC transactions are excluded from AMP by the product manufacturer selecting to use the Multiple Best Prices reporting approach for VBCs under CMS rules. In this scenario it is assumed that the VBC rebates 100% of the Wholesale Acquisition Cost (WAC) if the gene therapy does not provide benefit above a pre-negotiated threshold, otherwise the developer receives WAC (ignoring channel costs and mark-ups). Further assuming that 2 of the 5 patients in the period trigger the rebate yields an average net price of $300K for Payer

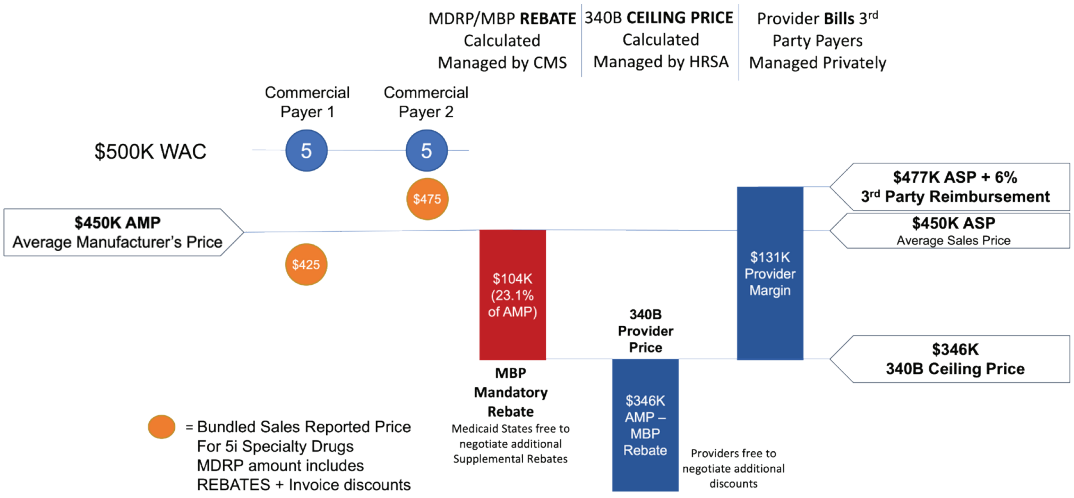

Figure 1. MBP to ASP and 340B: Discounted sales connection

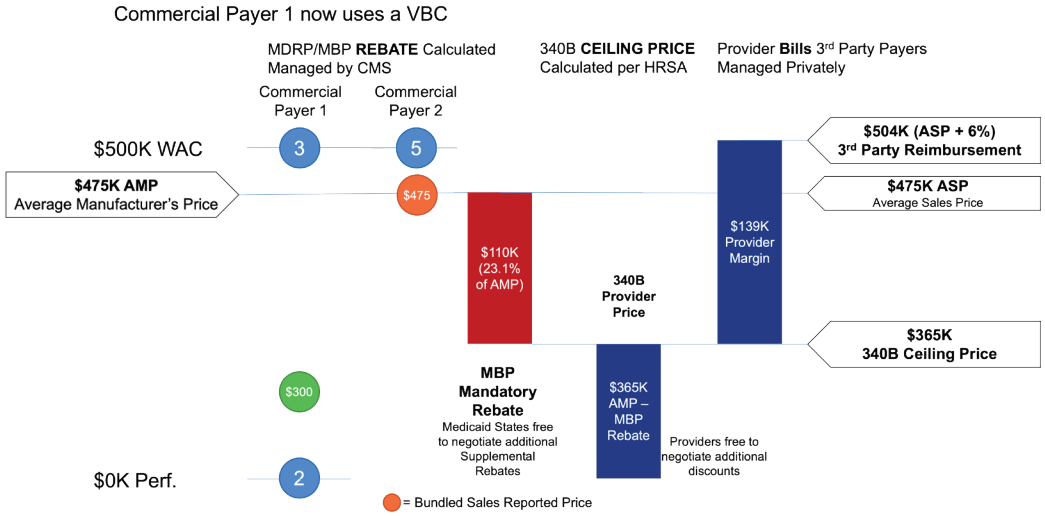

Figure 2. MBP to ASP and 340B: Discounted sales connection with addition of VBC that is excluded from AMP and ASP.

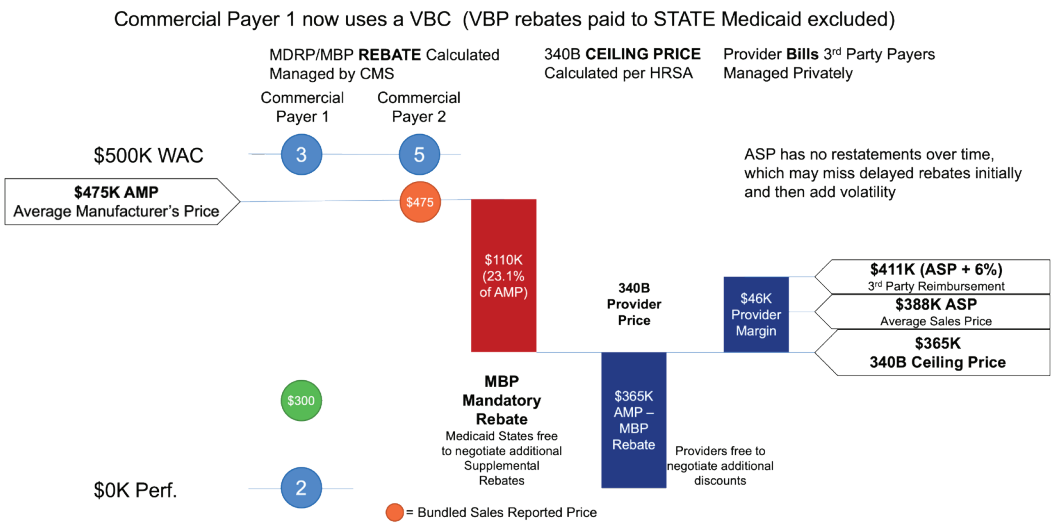

Figure 3. MBP to ASP and 340B: VBC excluded in AMP but included in ASP (which affects provider incentives to use therapy)

1 (3 patients at $500K WAC and 2 patients at a $0 net price). Under CMS rules the VBC transaction is excluded from the AMP calculation.

Thus, only the $475K average net price from Commercial Payer 2 is reported and included in AMP (Figure 2). Note that AMP may increase or decrease when excluding VBC related sales according to the negotiation strength of the payers. The higher AMP in this case results in a higher MBP mandatory rebate ($110K versus $104K; red bar) and a higher 340B ceiling price ($365K versus $346K; left dark blue bar). If the VBC is *also excluded* from the ASP calculation, ASP rises to $475, aligning to AMP, and leading to a higher provider reimbursement from commercial payers ($504K or ASP + 6%; right dark blue bar) using the same payer reimbursement assumption from above. The final provider margin thus also grows slightly to $139K (right dark blue bar).

In this example, the provider slightly wins financially, the developer received less because the higher 340B ceiling price likely does not offset the lower net VBC revenue, and some commercial payers might pay less and others more depending on their VBC performance rebates.

MIGHT INCLUDING VBC TRANSACTIONS IN ASP REDUCE PROVIDER MARGINS AND SO ALSO PRODUCT USE?

VBC transactions *are included in ASP* under current law. For providers, this significantly changes the net financial outcome as shown in Figure 3. By including the VBC transactions, ASP falls to $388K from $475K previously reported. So, while the mandatory MBP rebate and 340B ceiling price remain the same as the previous VBC case (Figure 2), the amount the provider receives from third party payers drops to $411 (ASP + 6%). In this scenario, the provider margin falls 65% from the baseline of $131K when no VBC was used (Figure 1) to $46K. Note that Figure 3 ignores the timing of VBC rebates on ASP and the resulting ASP volatility.

This margin reduction might incentivize providers to select other therapies in the class (if available) without VBCs to receive a higher margin. The fear of losing market share due to providers preferring higher margin competing products could then discourage developers from offering VBCs to payers.

Commercial payer benefits due to VBC inclusion in ASP may also be minimal in practice due to this potential provider behavior of therapy switching. The commercial payer tailwinds due to lower provider reimbursement (resulting from lower ASP) and VBC performance rebates will be offset by lower demand from providers. So, in the real world, commercial payers' total spend likely declines modestly.

Medicaid payers not participating in the VBC are mostly unaffected as they receive the same or higher mandatory rebates and generally reimburse a provider based on the provider's actual acquisition cost (AAC) of the therapy.

COULD VBC VOLATILITY TRIGGER IRA INFLATION REBATES?

VBCs may also increase ASP volatility. This places developers at risk of posting price increases that exceed the inflation rate for Medicare Part B or Part D covered gene therapies that then require additional mandatory rebates under the Inflation Reduction Act[5]. For most products IRA inflation rebates are approximately equal to the entire amount above the rate of inflation plus 6%.

Repurposing numbers from the above examples, imagine that an initial quarter results in a $388K ASP as in Figure 3 above. Then imagine that in the next quarter that Commercial Payer 1 has 0 of the 5 patients trigger the performance rebate due to statistical "luck". That next quarter then has an ASP of $488K–the average of Payer 1 at WAC and Payer 2 at $475K. The price increase for purposes of the IRA Inflation Rebate Program is thus almost 26% ($100K increase/$388K ASP in initial period). If inflation were

at 5% the maximum increase allowable before triggering the IRA Inflation Rebate is 11% (5% inflation + 6% maximum allowable increase). In this example, the added rebate the developer would have to pay CMS for EACH Medicare sale would be $57K ($488K - $388K*111%). Note that this Inflation Rebate is entirely due to volatility induced by the VBC and NOT because of any actual price increase.

Further, this new, lower, maximum price of $431K ($388K*111%) for the second quarter would become the base for the next quarter. Thus, the IRA Inflation Rebate volatility could further discourage developers from using VBCs.

POTENTIAL VBC CHALLENGES AND SOLUTIONS

Including VBC transactions in the ASP calculation likely discourages developers from entering into VBCs for fear of providers preferring other products with higher margins, especially where other products exist in the same class. The risk of increased ASP volatility along with associated IRA inflation rebates alone might create a VBC disincentive.

A congressional bill has been entered which would change the ASP calculation to match the AMP calculation and to resolve this dis-incentive.[6]

In addition, the marketplace is beginning to adapt to the VBC implications. For instance, patients often receive treatment on an outpatient basis through Centers of Excellence, which are often 340B eligible providers. For those 340B sales for which the developer receives lower revenue, the developers possess a reduced rebate and discount "pool" remains to share with payers. Payers and developers are increasingly recognizing that VBC rebate tiers be based on developers 340B net revenue, not the payer reimbursement to providers. VBCs thus yield less performance protection for payers.

Using VBCs to achieve full, FDA indicated, patient access likely will not occur until these challenges are addressed.

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ABOUT FOCUS

The NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

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