The Need for Value Based Contracting for Pharmaceutical Companies and Challenges in the Current Environment

For:

Clients and Friends of D2 Pharma Consulting, LLC and Riparian, LLC

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1.0 The Need for Value Based Contracting and Challenges in the Current Environment

1.1 Overview and Circumstances Leading to Rise of VBCs

In 2018, drug prices have remained a constant topic for scrutiny as they come under attack from payers, patients, and politicians. With the ongoing concerns regarding drug price increases, drug accessibility, and improving outcomes there is increased pressure on different stakeholders to better manage the increasing costs of healthcare products. President Trump's "American Patients First" plan has attempted to address this topic, calling for regulatory changes and tasking pharmaceutical manufacturers ("Manufacturers") to respond with more affordable pricing strategies. One of the proposed solutions to the above challenges is Alternative Payment Methods ("APMs"), or value-based contracting.

Aligning pharmaceutical and reimbursement around "value" instead of volume is seen by many in healthcare as the answer to affordability and sustainability in today's healthcare marketplace. The initial interest and shift toward outcomes-based contracting, in which a drug's pricing discounts are tied to the outcomes of a patient population, was seen in 2009 with the Merck Januvia contract. With the additional onset of key legislation under the Affordable Care Act of 2010, many more Manufacturers have attempted to gain a competitive edge by offering up such innovative contracts with insurers and pharmacy benefit managers. As of June 2018, there are over 31 private and public outcomes-based contracts in place.[i] As the growing trend of targeted, high-cost therapies for small patient populations continues to grow, the need to devise pricing strategies that reflect the efficacy of products will be imperative. There will be many regulatory and data limitations which must be overcome as the implementation of outcomes-based contracts continues to expand over a larger scope of healthcare products in the US, and as their design becomes more innovative and complex. However, as pricing and accessibility remain ever-present topics for discussion, the importance of understanding and utilizing value-based contracts cannot be overstated.

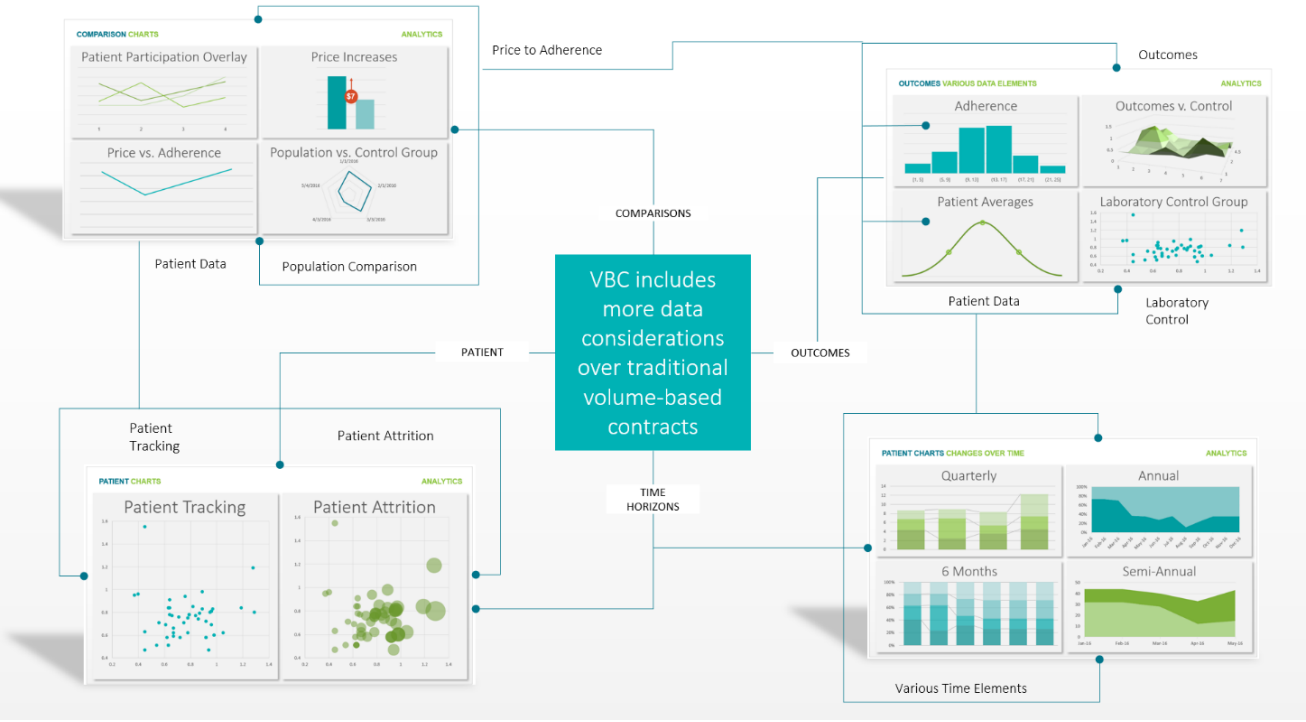
1.2 Current VBC Arrangements

Many of the current value-based or outcomes arrangements are designed by taking into consideration regulatory issues on the rebates, the capture of appropriate data related to healthcare products outcomes, and payers limitations to move away from some sort of volume-based rebate contracts on many existing pharmaceutical products.

Many value-based contracting arrangements may require data that measures product outcomes which are not available in traditional claims and lab data captured by payers. Payers are reluctant to set up contracts to include data elements that are difficult or costly to track and measure. Additionally, patient outcomes of many products such as cholesterol related drugs often take several years to evaluate. Consequently, payer data systems with high patient attrition in individual health plans prevents tracking large patient cohorts in a multiyear outcomes analysis for contracting purposes.

There are also payer limitations in the "richness" of unique datasets or the cost to collecting such data outweighs the possible discounts of the outcomes contracts. Often payers and Manufacturers use surrogate claims data in place of real world contract data. There is also a desire by payers to measure yearly data points which will provide yearly discounts and drive yearly profit margins. Another key dynamic is the unwillingness of payers to reduce the current volume rebates they receive from Manufacturers on existing products to a model that is totally based on outcomes and rebates. Manufacturers of existing products in a formulary are often offering a mix of contracts with the combination of base and outcomes rebates discounts. Manufactures with new or unique products who develop better strategies can achieve better payer access by launching a product with an innovative outcomes-based contract versus volume-based rebates while maintaining profit margins.

Figure 1.2.1: Complex data points needed to operationalize VBC agreements



Perhaps the greatest challenges to be solved are the current legislative and regulatory issues. Some of these are explained in detail in subsequent paragraphs.

1.3 VBC in Current Regulatory Environment— Limitations to VBCs

The current legislative and regulatory environment presents challenges to the implementation of value-based contract ("VBC") arrangements on a few fronts.

a. Anti-Kickback Statute/ Discount Safe Harbors

The Anti-Kickback Statute ("AKS") authorizes penalties against anyone who knowingly and willfully solicits, receives, offers, or pays remuneration, in cash or in kind, to induce or in return for (a) referring an individual to a person for the furnishing, or arranging for the furnishing, of any item or service for which payment may be made in whole or in part under a Federal health care program, or (b) purchasing, leasing, ordering, or arranging for or recommending purchasing,

leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Federal health care program.[ii]

The intent of the AKS is to prevent improper inducements that may lead to unnecessary and/or inappropriate care. Recognizing that certain arrangements are not intended to provide improper inducements to providers, the AKS includes statutory exceptions, commonly referred to as "discount safe harbors", permitting certain categories of remuneration activities. However, the current discount safe harbors do not contemplate VBCs that establish pricing on the basis of value metrics. Indeed, in the U.S. Department of Health and Human Services Office of Inspector General's ("OIG") most recent Semiannual Report to Congress, the OIG acknowledged the receipt of various proposals that would protect VBC arrangements, stated that it is not adopting the suggested proposals as they require further study, and indicated that questions relating to the application of the AKS to VBC arrangements should be addressed on a case-by-case basis.[iii] This reactive "case-by-case" approach creates significant challenges for Manufacturers seeking to engage in VBC discussions with third parties, in particular because such arrangements often require coordination and data sharing between the Manufacturer and third parties on patient outcomes.

b. Government Program Discount Obligations and Pricing Issues

Most Manufacturers participate in Federal and state government programs that require those Manufacturers to, directly or indirectly, provide minimum discounts on certain sales of their drugs and/or therapies, where such discounts are determined on the basis of self-reported prices (along with other data). Often referred to as "Government Pricing Programs", these programs include the Medicaid Drug Rebate Program ("MDRP"), 340B Drug Pricing Program, and the Medicare Part B Price Reporting Program.[iv]

i. Medicaid Drug Rebate Program and 340B Drug Discount Program

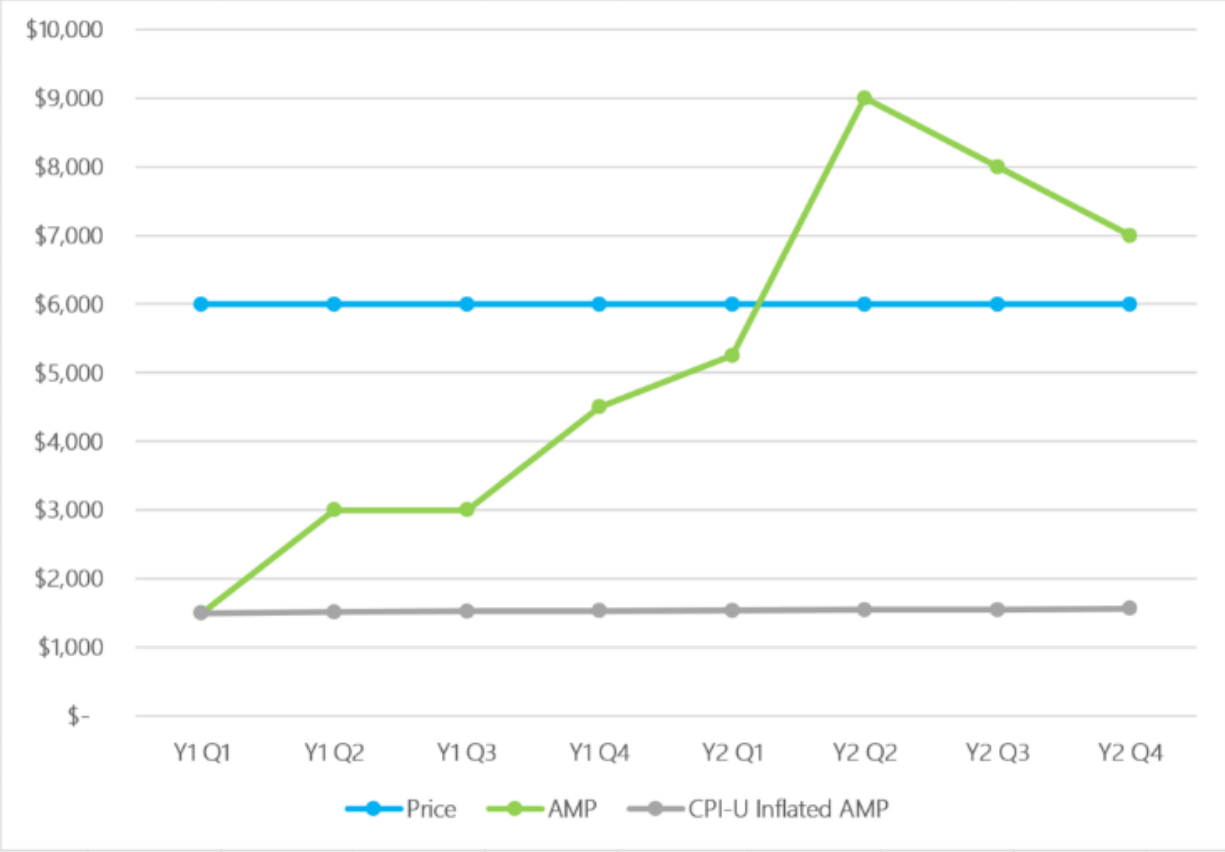
The MDRP is designed such that a single quarterly unit rebate amount ("URA") is determined for each distinct dosage form and strength of a covered outpatient drug, and is applied to all units of the covered outpatient drug dispensed or administered to Medicaid beneficiaries (including patients for which Medicaid is the secondary payer). The URA formula is comprised of two key components – 1) a basic rebate component, and 2) an additional component commonly referred to as the "CPI-U penalty".

The basic rebate amount is equal to AMP multiplied by a minimum rebate

percentage (23.1% or 17.1% for blood clotting factors and drugs approved by the Federal Drug Administration exclusively for pediatric indications), or AMP minus BP – whichever is greater.[v] For this reason, Manufacturers pay close attention to their Medicaid BP, and even establish discounting "guardrails" in their contracting policies in an effort to preserve their BP. These sorts of "guardrails" apply to VBC arrangements as well; in general, Manufacturers cannot structure a VBC that makes available a discount greater than the Medicaid minimum rebate percentage without running the risk of a single unit under that arrangement triggering the maximum discount, which would then lower the Medicaid BP and increase the basic rebate applicable to all units subject to a Medicaid rebate. In other words, the current requirements pertaining to Medicaid BP can generate an outcome that is completely contrary to the underpinning of a VBC that is premised on risk-sharing; a steep discount on drug(s) that did not generate the expected value for a patient translates into that same steep discount applied to all covered outpatient drugs dispensed or administered to Medicaid beneficiaries, irrespective of outcomes.

Both components of the URA formula – the basic rebate component as well as the "CPI-U penalty" component – are determined using Medicaid AMP. AMP presents a different challenge, separate and apart from the limitation/ risk associated with offering discounts that are greater than the Medicaid minimum rebate percentage caused by BP. In general, Manufacturers cannot structure a VBC that makes available patient "outcomes based installment payments" without incurring a URA that is effectively equal to giving away every Medicaid unit at $0.00 via a rebate that is equal to AMP. This is because AMP is the average price paid to the Manufacturer in a quarter. In the event the average price paid is initially only a fraction of the total potential price of the drug due to the use of installment payments, AMP in the first few periods following product launch will be low and then increase quickly upon receipt of subsequent installment payments. The "CPI-U penalty" component of the URA calculation is designed to penalize Manufacturers for taking price increases that outpace the CPI-U rate of inflation over time; specifically, this component of the URA calculation applies an additional rebate equal to the difference between the AMP calculated for the URA quarter and the CPI-U adjusted Baseline AMP (i.e., AMP for the first full quarter the drug is on the market). The use of installment payments will likely yield a Baseline AMP that is very low and subsequent quarterly AMPs that will significantly outpace the CPI-U rate of inflation over time – even in the absence of any price increases being taken.

Figure 1.3.1: Example Impact of Installment Payments on AMP in Current Regulatory Environment

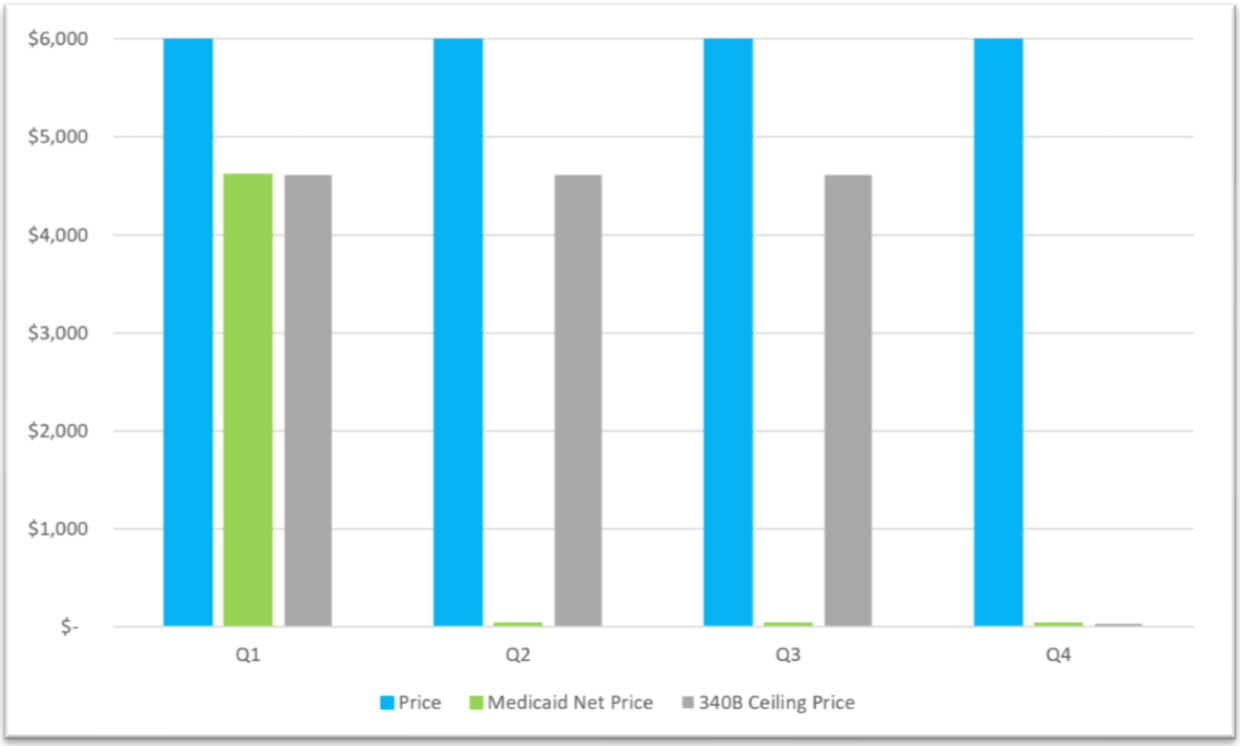


This graph shows an example where the full price of a single vial of product is $6,000 payable over four equal installment payments of $1,500, where one unit of the product for each installment payment is considered one vial. An AMP calculated using guidelines in today's regulatory environment will result in an artificially low Baseline AMP, and apparent increases in quarterly AMP values in subsequent quarters that outpace the CPI-U index, even absent an actual price increase. Depending on the variability in the number of units sold per quarter, the current calculation method may even yield an AMP that is higher than the actual price of the drug.

These issues are further exacerbated by the fact that the 340B Drug Pricing

Program establishes obligatory discounts in the form of ceiling prices that Manufacturers must extend to 340B covered entities on their covered outpatient drug purchases, which are tied to Medicaid pricing – specifically Medicaid AMP minus URA. In the event the Medicaid URA is equal to the AMP by virtue of a high basic rebate amount (caused by a low BP) and a high additional rebate (caused by a low Baseline AMP relative to quarterly AMP), a Manufacturer may find itself in a position where it is effectively giving away every unit purchased by a 340B covered entity by virtue of the 340B ceiling price being discounted down to a penny.[vi]

Figure 1.3.2: Example Impact of VBC Arrangement on Medicaid and 340B Prices in Current Regulatory Environment



The above graph illustrates a scenario where the Medicaid net price is discounted at 100% as a result of a VBC beginning in Q2, followed by a drop in the 340B Ceiling Price to penny pricing two quarters later.

ii. Medicare Part B Average Sales Price ("ASP") and ASP-Based Payment Limits

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA") established, among other things, a new payment methodology for physician-administered drugs and biologicals covered by Medicare Part B. By doing so, the MMA replaced the payment methodology based on average wholesale price ("AWP") (which many argued was not reflective of actual prices paid by providers and was as a result subject to long-standing concerns around fraud and abuse) with a payment methodology based primarily on ASP, which reflected actual prices paid by providers.

Similar to the challenge presented by AMP described in the above, the use of ASP as a payment limit creates a challenge around implementing value-based pricing effectuated via installment payments. This is because ASP, similar to AMP, represents the Manufacturer's average price of sales during a quarter. In the event the average price paid is initially only a fraction of the total potential price of the drug due to the use of installment payments, ASP in the first few periods following product launch will be low, and will result in providers being under-reimbursed for products that are purchased at the full price, which may then lead to patient access issues.

1.4 Future State— Changes that Could Foster VBCs

The following are a few proposals that could address the challenges described in this paper.

a. Anti-Kickback Statute/ Discount Safe Harbors

Include a statutory exemption for VBCs that provides for discounts in the event measurable patient outcomes are not achieved, and/or issue regulations that clearly establish the parameters of permissible VBC arrangements. Such a change would enable Manufacturers to deploy their resources toward crafting VBC arrangements that they can have full assurance will not violate the AKS, so as to avoid expending resources toward an approach that may need to be significantly revised and/or even disposed of, after being evaluated by the OIG.

b. Medicaid BP

Exempt value-based pricing from the determination of Medicaid BP, in exchange for the same value-based pricing arrangement being offered to Medicaid. Such a change would afford Manufacturers the ability to offer discounts far exceeding

23.1% on those units that do not achieve the agreed-upon outcomes – without forcing those same discounts on every Medicaid and 340B unit.

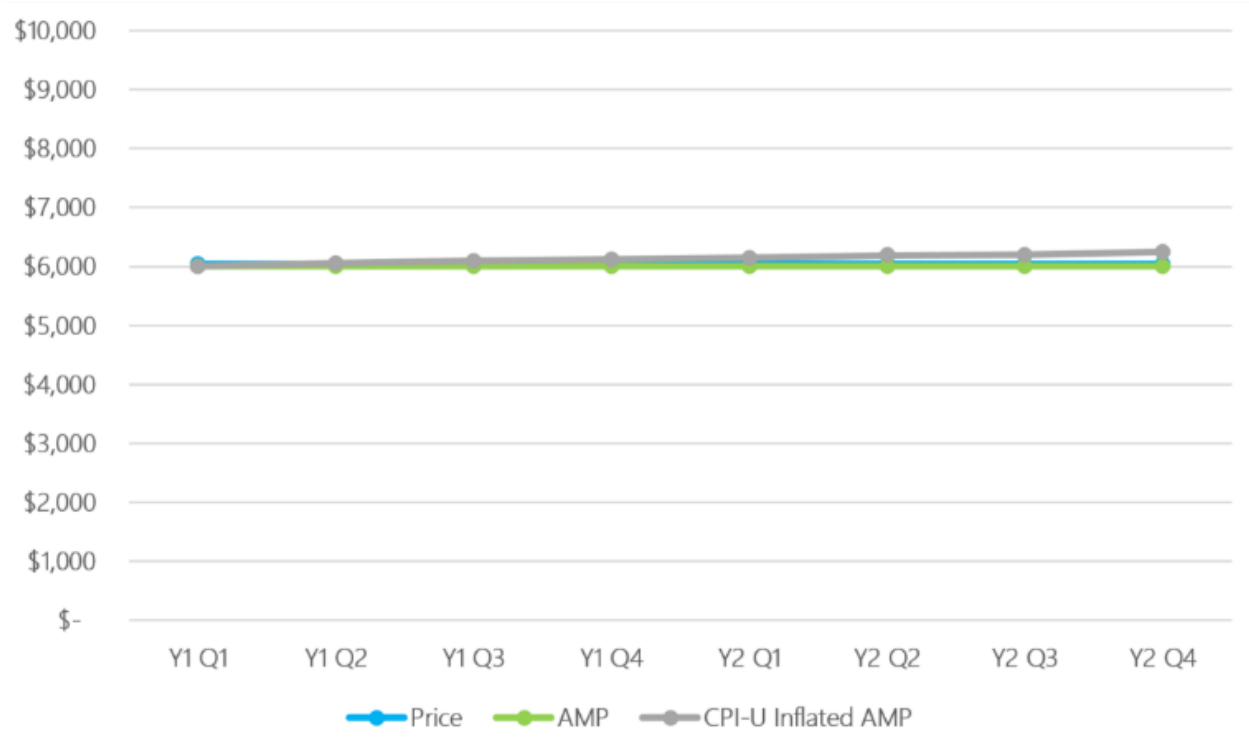
c. Medicaid AMP and Medicare Part B ASP

Revise the AMP and ASP definitions in a manner that permits sales subject to installment payments to be prorated over the installment payment milestones. Using the same example in Figure 1.3.1 where the full price of a single vial of product is $6,000 payable over four equal installment payments, only 25% of the vial quantity would be accounted for in the period in which each installment payment is made – such that the initial installment payment of $1,500 would be attributed to a 0.25 vial, rather than the entire vial of product. The following table contains an example of the manner by which the remaining installment payments could be taken into account:

	Period 1: Initial sale/ first installment payment due	Period 2: Second installment payment due	Period 3: Third installment payment due	Period 4: Fourth installment payment due
Payment	$1,500	$1,500	$1,500	$1,500
Unit	0.25 vial	0.25 vial	0.25 vial	0.25 vial

Such a change would enable Manufacturers to implement installment payment arrangements without generating nonsensical AMP and ASP results that would detrimentally impact their MDRP and 340B program discount liabilities and/or create provider reimbursement challenges that may result in patient access issues.

Figure 1.4.1: Impact of VBC on AMP Using Potential Alternative Calculation Method



As a contrast to Figure 1.3.2, this graph illustrates an alternative calculation method where sales subject to installment payments are prorated over installment payment milestones, yielding an AMP consistent with the price.

d. Limiting Medicaid Rebates When Medicaid is a Secondary Payer

Establish a limit on Medicaid rebates when Medicaid is a secondary payer – specifically, limiting the rebate amount due to the Medicaid reimbursed amount in the event the calculated rebate exceeds the reimbursed amount. Such a change would rectify the financial inequality that is created when the Medicaid rebate exceeds the Medicaid reimbursed amount – especially if Medicaid as the secondary payer is receiving the benefit of a discount under a VBC arrangement.

1.5 Conclusion

Value based contracts have the real potential to solve some of the key issues around affordability and sustainability when it comes to the provision of healthcare in America. However, there are various systemic and regulatory limitations that will need to be addressed in order encourage broader acceptance of value based payment models. Absent such systemic and regulatory change, a widespread adoption of value based pricing will continue to be stymied in light of the operational complexity of implementing these types of arrangements as well as potential legal and financial risks that Manufacturers face as a result of entering into such arrangements. Manufacturers considering adopting VBC agreements in the current regulatory environment are encouraged to consult with their legal and business advisors to discuss the potential impacts of such arrangements on their Government Pricing Programs discount obligations.

2.0 References

i. D2 Pharma Consulting, LLC market research.

ii. Social Security Act § 1128B(b) [42 U.S.C. § 1320a-7b].

iii. U.S. Department of Health and Human Services Office of Inspector General ("OIG") Semiannual Report to Congress for October 1, 2017 - March 31, 2018 (https://oig.hhs.gov/reports-and-publications/archives/semiannual/2018/sar-spring-2018.pdf, last accessed on September 19, 2018).

iv. Only those programs that are further discussed and directly relevant to this paper are listed here.

v. This applies to drugs that are categorized as sole-source innovator drugs ("S drugs") or innovator multiple-source drugs ("I drugs") for purposes of the MDRP, generally brand drugs.

vi. The 340B ceiling price for a covered outpatient drug is equal to Medicaid AMP minus the URA. The exception to this requirement is when the ceiling price calculation results in an amount less than $0.01; when this occurs, the ceiling price will be $0.01. [42 C.F.R. § 10.10(b)].

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