PHARMACEUTICAL CONTRACTING:
FROM VOLUME TO VALUE

Robert Blank,
Managing Consultant
EVERSANA

EVERSANA™

Driven by skyrocketing costs, market forces are hastening the shift in the healthcare industry from volume-based care (fee for service) to a value-based reimbursement structure (fee for value). While the inertia of entrenched policies, regulations, organization structures, and systems have held back the tide, industry analysts agree that the tipping point is being reached.[1][2][3]

The evolution towards this model is accelerating as patients, healthcare providers and payers realize its many benefits. The "value" in value-based healthcare is derived from measuring health performance metrics against the cost of delivering those metrics. These reimbursement models encourage healthcare providers to deliver the best care at the lowest cost. In turn, patients receive a higher quality of care at a better value.

In response, in the pharmaceutical industry, attention has recently focused on exploring and establishing value-based (sometimes called "risk based" or "innovative") contracts between manufacturers and their customers. In these arrangements, payments are predicated upon measurements of patient welfare, rather than increasing purchase volumes or market share. While the possibilities suggested by these agreements are undeniably appealing, manufacturers need first to consider their readiness to support them, in addition to any downstream implications. By proactively assessing proposed contracting strategies, manufacturers can mitigate potential risks while confirming the operational capabilities necessary for success.

BACKGROUND

Contracting Scenarios

The deal structures considered to be "value based" vary in definition, but are generally comprised of rebates paid from pharmaceutical manufacturers to their customers that are contingent upon achievement of a negotiated performance metric.[4] Unlike traditional access or market share rebates however, these arrangements are intended to incentivize better patient care and outcomes. The result is mutually beneficial for both contracted parties, as manufacturers can ensure their product is being used successfully and consistently, while their customers can help foster a healthier patient population, decreasing the number of claims paid for medical emergencies and long-term care. While insurance companies and Pharmacy Benefit Managers (PBMs) have been some of the earlier adopters of these models, their success will likely entice other industry stakeholders to pursue them in their contracts with manufacturers as well.

One of the more popular varieties being considered by the industry is an "outcomes" model, wherein the determination of payer reimbursement from a manufacturer is made based on the efficacious use of a drug through a trackable measurement. For example, the success of a statin drug could be ascertained by the regular provision of the cholesterol levels for patients taking the medication. The manufacturer would then be compelled to pay a rebate to the PBM if the covered patient population did not meet the targeted cholesterol level.

CONTRACTING SCENARIOS

Figure 1 - The table below depicts an example of how an outcomes based rebate model might be structured for a contract between a manufacturer and PBM

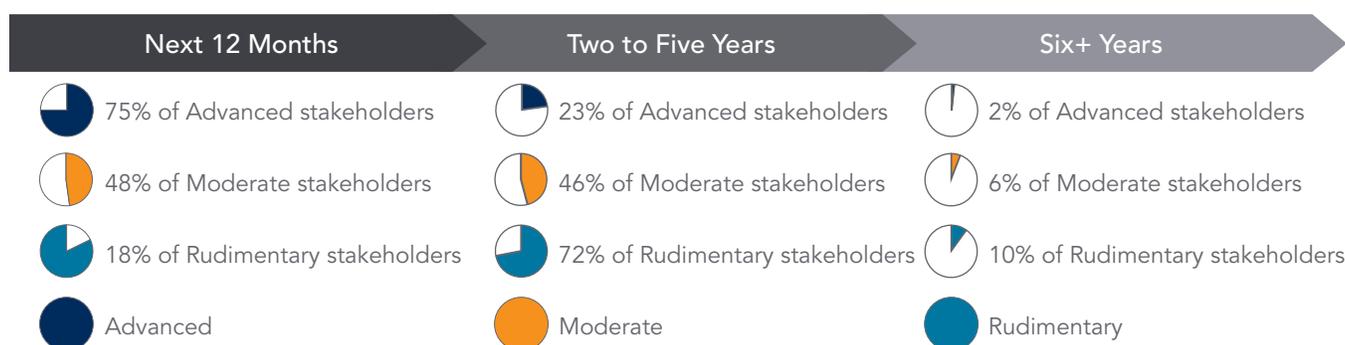| Tier	% of Patient Group with Cholesterol < 200 mg/dL	Rebate
1	> 80%	0
2	75.1% to 79.9%	5%
3	< 75%	10%

Another type of agreement is an "adherence" model, where payments are made according to the consistent usage of product by covered individuals within a plan or set of plans. For example, the appropriate usage of a hypertension therapy could be measured by tracking the monthly prescription refills of patients taking the drug. The manufacturer would then agree to pay a rebate to the PBM if the covered patient population maintained an acceptable level of utilization. Alternatively, such an arrangement could award increasing rebates for growth in the average patient adherence level, as shown in the example below.

Figure 2 - The table below depicts an example of how an adherence based rebate model might be structured for a contract between a manufacturer and PBM

Tier	% Increase in Therapy Completion from Prior Year	Rebate
1	0 to .99%	0
2	1.00% to 1.99%	2%
3	≥ 2.00%	4%

These deal structures represent only a handful of agreement types being explored, many of which grow increasingly more complex. As more bundled products, temporal clauses, and contingent discounts are layered into a contract, more scrutiny is required to ensure that the arrangement is actionable and compliant. While these considerations have dissuaded some manufacturers, recent research indicates that more industry stakeholders are gaining the ability to handle these terms, likely increasing their desire to contract in such a manner.

Figure 3 - The figures below show the average time indicated by payers and providers required to achieve necessary capabilities in value based contracting[5]

Next 12 Months	Two to Five Years	Six+ Years
75% of Advanced stakeholders	23% of Advanced stakeholders	2% of Advanced stakeholders
48% of Moderate stakeholders	46% of Moderate stakeholders	6% of Moderate stakeholders
18% of Rudimentary stakeholders	72% of Rudimentary stakeholders	10% of Rudimentary stakeholders
Advanced	Moderate	Rudimentary

Source: Health Strategies Group Risk-Based Contracting Outlook, May 2017

OPERATIONAL CHALLENGES

Data & Systems

Appropriate data must be provided to measure rebate qualification successfully. By default, utilization files provided from PBMs may not contain all the necessary information to calculate achievement of value based criteria. For example, while data files will generally contain the prescription IDs and refill numbers to track adherence, they won't contain the patient information needed to measure outcomes. Addressing this need will entail the addition of new data fields, requiring testing from technical analysts, or providing additional files, increasing strain on business analysts.

Value-based agreements also require more robust functionality from a revenue management system. As contracting strategies have evolved over the years, so too have the platforms processing them. While most systems support tiered pricing and rebate structures, they're not always able to handle the calculation of associated performance measurements, as shown in the figure below. In these cases, achievement determination happens outside the system and is manually adjusted after calculation. As many value-based strategies involve even more complex performance bases, current generation systems are often not capable of the associated measurements. Exacerbating this is the volume and variability of value-based terms being evaluated, making it difficult for software vendors to standardize them.

Figure 4 - The picture below shows examples of the relative complexity of various contracting strategies, from simple to more intricate, and the ability for systems to handle them

Fixed
Example:
$95 per unit

Dynamic
Example:
20% off

Volume Tiers
Example:
100 units sold =
15% off
200 units sold =
20% off

Market Share Tiers
Example:
60% market share =
10% off
65% market share =
15% off

Value Based Tiers
Example:
2% growth in days on
therapy = 15% off
3% growth in days on
therapy = 20% off

COMPLEXITY: High / Low

RMS WITH REQUIRED FUNCTIONALITY: All / Most / Many / Few / Very Few

Government Pricing

Pharmaceutical manufacturers are required to calculate a variety of reference prices for the government to access and negotiate preferential pricing. Among these is Best Price (BP), calculated quarterly, which is defined as the "lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States."[6] BP is often a concern for manufacturers, as it is used to set contingent price points for certain government programs and institutions. Once calculated, BP can be used to set the Unit Rebate Amount (URA) for all Medicaid utilization. This URA is then subtracted from the Average Manufacturer Price (AMP) to set the ceiling price for the 340B Drug Pricing Program, which sets the acquisition cost for a variety of government subsidized entities.

Given the far-reaching effects of setting BP, the variability of value based agreements can pose unique challenges to its calculation and predictability. Unlike other pricing calculations, many of which are averages, BP must be calculated on a per unit basis. As a result, all applicable discounts for a sold product must be added or "stacked" together to derive a singular price point.

Figure 5 - The chart below displays an example of how drug discounts are stacked on top of one another to calculate a per unit cost for the Best Price calculation

NDC-11	Sales		Discounts			Best Price
	Dollars	Units	Base Rebate	Admin Fee	Price Protection	Per Unit
86753090001	$ 639,360.00	10,368	$ 420,380.00	$ 25,574.40	$ 5,724.36	$ 18.10

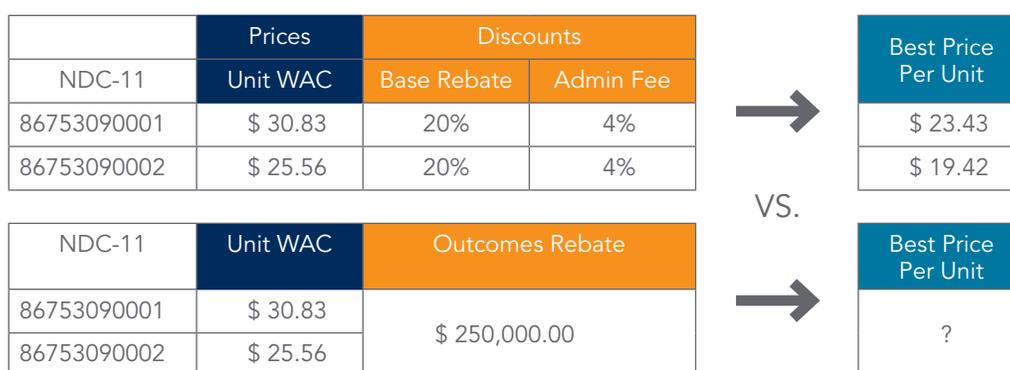$$[\ \$639{,}360.00\ -\ \$451{,}678.76\ ]\ \div\ 10{,}368\ =\ \$18.10$$

Thirty days after the end of a quarter, BP must be provided by pharmaceutical manufacturers to the Center for Medicare and Medicaid Services (CMS). While many direct and indirect sales, along with any upfront discounts, will be settled by this time, many rebates will still be outstanding, as the relevant data is collected and provided several weeks after the period has ended. Further complicating matters is that many customers will send new or corrected data even months later in subsequent submissions. Since BP is based on when a discount was earned, rather than when it was paid, a process was created to allow for manufacturers to restate their calculations to account for this time delay. As a result, the "initial" BP is frequently calculated based on what is offered on contracts, then reconciled after all data is available into an "actual" BP, based on what was transacted. Traditional deal structures are fairly predictable for this calculation, as the discounts operate on a fixed percentage or fixed dollar value.

Figure 6 – The picture below shows how the initial BP calculation occurs earlier than some of the relevant data for that period is available or paid

Prescriptions Filled	1Q BP Calc Due 4/30/2019	1Q Rx Data Provided 5/15/2019	1Q Rebate Paid 6/14/2019	Additional 1Q Rx Data Provided 8/15/2019
1Q 2019		2Q 2019		3Q 2019

The problem posed by BP for certain value based arrangements is the unpredictability of the per-unit price ahead of time. For example, if an annual payment of $250,000 is offered by manufacturers to PBMs for successful completion rates of a drug therapy, it is unknown how many units will have to be applied to that sum until the measurement period ends.

Figure 7 – The images below show the difficulty in attaining a per-unit price for certain value based arrangements prior to utilization data being available, as compared to more traditional rebates

	Prices	Discounts		Best Price Per Unit
NDC-11	Unit WAC	Base Rebate	Admin Fee	
86753090001	$ 30.83	20%	4%	$ 23.43
86753090002	$ 25.56	20%	4%	$ 19.42

VS.

NDC-11	Unit WAC	Outcomes Rebate	Best Price Per Unit
86753090001	$ 30.83	$ 250,000.00	?
86753090002	$ 25.56		

Other value based agreement types can cause even more precarious scenarios. For example, if a manufacturer agrees to cap a payer's spend past a certain limit, or fully reimburse a payer if a drug does not produce expected results in a patient population, it could be argued that the products were provided at a Best Price of zero. If this was the consensus of the government as well, massive price concessions would be incurred for Medicaid utilization and purchases under the 340B Drug Pricing Program.

The aforementioned examples are just some of the ways value based agreements can challenge government pricing calculations. Every scenario varies considerably based on the deal structure, products, and pricing offered.

Any prospective arrangements should always be reviewed with internal and external legal counsel to ensure that the terms are consistent with existing legislation, rulings, and assumptions.

Discount Reallocation

Because of existing regulations, contingent product discounts often must go through a process of reallocation before being factored into government pricing calculations. These product groupings, commonly referred to as bundles, were recently defined by CMS as "any arrangement … under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types … or another product or some other performance requirement … or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement." The rule goes on to say that the discounts provided from these arrangements must be "allocated proportionally to the total dollar value of the units" contained within the bundle[7].

Figure 8 – The picture below shows an example of how discount reallocation occurs for bundled arrangements where discounts for one product are contingent upon another product

	Sales	Discounts		Discount Reallocation	
NDC-11	Dollars	Base Rebate	Volume Rebate	Sales %	Reallocated Rebate
86753090001	$ 725,760.00	$ 145,152.00	$ -	51.95%	$ 153,870.42
86753090002	$ 671,310.00	$ 134,262.00	$ 16,782.75	48.05%	$ 142,326.33
Total	$ 1,397,070.00	$ 279,414.00	$ 16,782.75	100.00%	$ 296,196.75

The process of discount reallocation adds yet another layer of complexity to government pricing operations for many value based agreements. For example, if a rebate is offered for every member of a plan, the requirement to spread discounts down to a product level can make Best Price determination less predictable. If the total number of members increases at a pace that is greater than that of the submitted units, the per-unit net price will be driven down. Over time, a continuation of this trend, or a sudden spike, could end up setting a new Best Price.

Figure 9 – The charts below show an example of how variable payment rates can impact Best Price calculations after the discounts are reallocated for the measured period

Discounts		
Member Rate	# of Members	Rebate
$80	18,184	$1,454,720.00

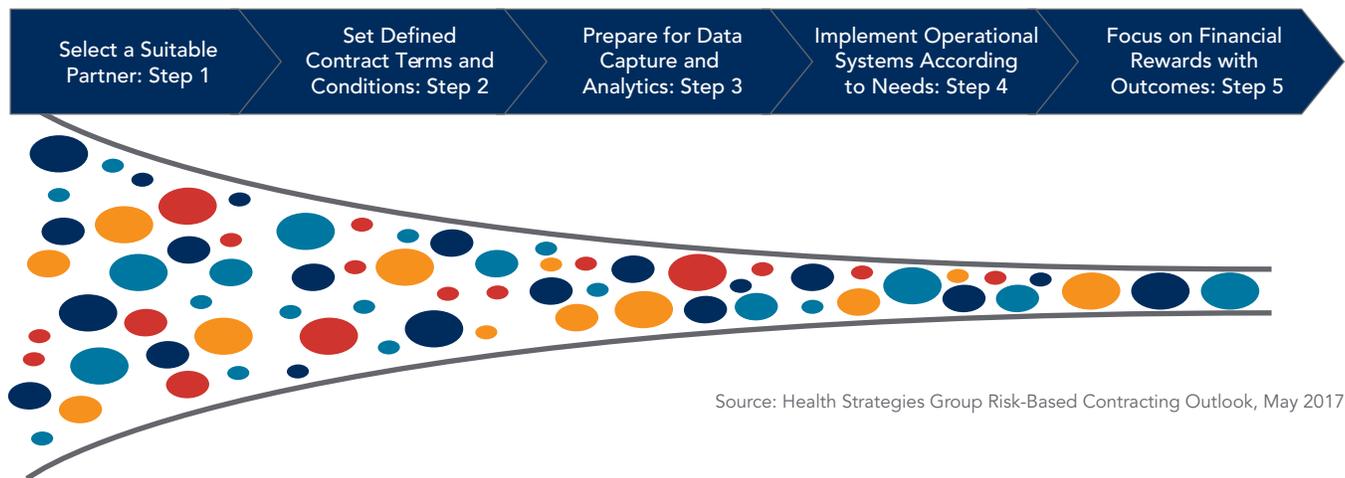|	Sales		Discount Reallocation			Initial BP
NDC-11	Dollars	Units	Sales %	Rebate	Unit Price	Unit Price
86753090001	$2,872,100.00	49,236	31.46%	$ 457,589.12	$ 49.04	$ 51.00
86753090002	$6,258,583.33	107,290	68.54%	$ 997,130.88	$ 49.04	$ 51.00
Total	$9,130,683.33	156,526		$1,454,720.00		

NEXT STEPS

Recommendations

As the industry inexorably heads towards a value based market, proactivity becomes increasingly more important. Examination of value based contract strategies in coordination with organizational readiness, operational capabilities, system capacity, and government pricing requirements will mitigate any potential issues before they occur. Once these have all been adequately assessed, companies need to determine the appropriate steps forward to ensure the best chances of success. While these will vary in duration and content for each organization, the overarching chronology will be similar for most companies, as depicted in the example below.

Figure 10 – The image below shows the high level steps that companies should take in the exploration and implementation of value based contracting[5]

| Select a Suitable Partner: Step 1 | Set Defined Contract Terms and Conditions: Step 2 | Prepare for Data Capture and Analytics: Step 3 | Implement Operational Systems According to Needs: Step 4 | Focus on Financial Rewards with Outcomes: Step 5 |

Source: Health Strategies Group Risk-Based Contracting Outlook, May 2017

Organizational Readiness

Before engaging in value based agreements, manufacturers should first obtain consensus among critical stakeholders after weighing the benefits and costs. Certain types of products and business models are more easily suited to making such a transition, and entry into these arrangements does not occur without growing pains. It is also critical to obtain clinical input and ensure that data can be regularly procured, reliably managed, and adequately measures the intended results. Failure to do so will ultimately result in contracts that cannot be operationalized and do not achieve their ambitions. Concurrently, it is important to select an appropriate contract partner who is equally committed to providing and measuring this data.[5] As a result, engaging in a "pilot" contract first is often advisable, prior to extending value based terms to all contracted entities. This provides an opportunity to test the feasibility of management and potential success of these arrangements with a limited amount of risk. In cases where risk is unavoidable, it should be shared equally among all contracted parties, and seek to benefit each equally as well.

Figure 11 – This chart shows how risk can be shared amongst contracted organizations to ensure conditions that are mutually beneficial[5]

Source: Health Strategies Group Risk-Based Contracting Outlook, May 2017

Operational Capabilities

When performance terms are proposed for earning a rebate, it is critical to ensure that they can be effectively operationalized. A methodology for how the metric is determined should be agreed upon by both parties to prevent any disparities in calculation from occurring. Once this methodology is determined, it is imperative to include the data fields and level of detail required for calculation within the contract. By achieving consensus on the performance basis and required formula data, manufacturers and their customers can safeguard against disputes when claims are processed.

System Capacity

Performing an assessment of RMS capabilities will quantify the types of deal structures that can be supported within the current system landscape. This can then guide contract negotiations to determine the arrangements that can be pursued without concern for operational readiness. Having reviews of proposed contract terms with operations and government pricing team members will further help to ensure that agreements are successful. As many systems lack the ability to manage and calculate more complex contracting terms, manual workarounds often need to be established to bridge the gaps. Ensuring that this appraisal occurs proactively will circumvent any system shortcomings in a more effective and sustainable manner.

Government Pricing Requirements

Given the downstream impacts of setting BP, taking precautions to prevent it from occurring inadvertently through a value-based agreement is advisable. Since Medicare utilization is excluded from BP calculations, partitioning value-based agreements to this channel, and precluding them from commercial Managed Care contracts, will prevent them from setting Best Price by default. If intended for use in commercial agreements, extending them to customers who have historically not set the Best Price will lessen the chance of it occurring in the future.

As an additional means of control, avoiding lump sum payments and variable payment ratios on value based agreements can reduce the risk of breaching best price. By setting reimbursement rates as a fixed, or tiered, percentage of revenue, the per-unit cost can be determined ahead of time; this can also prevent discounts from needing to be reallocated.

In cases where these measures are not feasible, payment caps can be a reliable method for controlling price points on agreements. For example, by capping reimbursement amounts to 23.1% of WAC, the chance is reduced for BP to outweigh AMP in the Medicaid URA calculation. In this case, even if the value-based agreement did set Best Price, it would not be used in the formula.

Figure 12 – The table below shows the standard Medicaid URA calculation and how Best Price can be used to set the reimbursement amount for Medicaid rebates

1	Basic Rebate = (> of AMP * (23.1%) or AMP − BP)
2	Adjusted Baseline = (Baseline AMP / Baseline CPI-U) ‡ Quarterly CPI-U
	Additional Rebate = AMP − Adjusted Baseline, if AMP > Adjusted Baseline
3	Total Rebate = Basic Rebate + Additional Rebate
4	If Total Rebate > AMP, then Total Rebate reduced to = AMP

Payment caps are especially useful in cases where the contracted benefit is not defined on a per-unit basis, as they help to regulate the potential BP impact, as well as providing predictable rates for BP initial calculation. Finally, the usage of "clawback" provisions, wherein reimbursed funds are recouped up to the threshold of BP, can help to mitigate the impact of value-based agreements when rates vary unexpectedly.

Conclusion

Despite the challenges imposed by existing legislation, the pharmaceutical industry continues to explore more innovative and value-based agreements. Failing to evaluate these terms properly can overburden resources, decrease profitability, and breach compliance with government regulations. Conversely, resisting adoption of these novel contracting strategies can mean losing out on market share in favor of competitors. Manufacturers, therefore, are best served by thoroughly assessing the various strategies, their operational readiness, and legal assumptions to ensure a seamless, informed, and successful transition into a new contracting landscape.

About the Author

Robert Blank, Managing Consultant

Mr. Blank's expertise lies in contracts, pricing, and reimbursement strategies and operations in the life sciences industry. He leverages his expertise to develop and execute revenue management and business process improvement plans for his clients.

REFERENCES

1. Forbes. (2017). As Drug Prices Soar, Value-Based Pay Hits Pharmaceutical Industry. Retrieved from: https://www.forbes.com/sites/brucejapsen/2017/05/31/as-drug-prices-soar-value-based-pay-hits-pharmaceutical-industry/#23cf15df493c

2. Optum. (2017). Navigating the Journey from Providing Care to Managing Health. Retrieved from: https://www.optum.com/resources/library/navigating-the-journey-providing-care-to-managing-health.html?s=5in5

3. Modern Healthcare. (2017). Value-based contracts key to solving U.S. drug pricing 'crisis'. Retrieved from: http://www.modernhealthcare.com/article/20170609/NEWS/170609875

4. Health Affairs. (2017). Value-Based Pricing For Pharmaceuticals In The Trump Administration. Retrieved from: https://www.healthaffairs.org/do/10.1377/hblog20170427.059813/full/

5. Health Strategies Group. (2017). Hengst, Nicole. Flushman, Howard. Risk-Based Contracting Outlook. Purchased from: http://healthstrategies.com/

6. Government Publishing Office. (1990). Omnibus Budget Reconciliation Act of 1990. Retrieved from: https://www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg1388.pdf

7. Office of the Federal Register. (2016). Medicaid Program; Covered Outpatient Drugs. Retrieved from: https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs