# MANUFACTURER RELATED VALUE-BASED CONTRACTS (VBC) – WORKING THROUGH "THE GNARLY DETAILS"

## Face Your Company's Sunshine Reporting, Best Price & Anti-Kickback Concerns Head On

Fall 2017

## Follow a Systematic Approach to Stakeholder Engagement, Real World Evidence &Compliance Management

*--by Terri Bernacchi, PharmD, MBA*

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## About the Author.


- Terri Bernacchi is the Founding Partner of SME Health Systems and Cambria Health Advisory Professionals. Terri has had a varied career in health related settings including: 9 years in a clinical hospital pharmacy setting, 3 years as a pharmaceutical sales rep serving government, wholesaler, managed markets and traditional physician sales, 3 years working for the executive team of an integrated health system working with physician practices, 4 years as the director of pharmacy for a large BCBS plan, 12 years of experience as founder and primary servant of a health technology company which was sold to IMS Health in late 2007. She has both a BS and a PharmD in Pharmacy and an MBA.
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*"In their most evolved state, these contracts reimburse based on outcomes, not volume. Each contract is different, but essentially, they tie reimbursement incentives or disincentives to how well a medication has performed against a benchmark. So, for these contracts to function, payers need to have population datasets that connect the dots between consumption and patient outcomes. Oftentimes these contracts create win-win incentive for manufacturers to do what they can to optimize the effect of the therapies for their patients. Costly medications will not reach their intended goals if patients are not adhering to the regimen. This is why value-based deals, requiring real-world evidence (RWE), are often paired with robust patient support programs that lift adherence rates."* ***The PharmaLetter. June 26, 2017.***

*"Standing in the way of more progress on the value-and-price front and testing these types of innovative contracts are regulatory hurdles that restrict communications between payers and manufacturers, as well as other barriers that currently create disincentives to paying for value."* ***Value Depends on Real-World Evidence July 28, 2017. D Leonard***

# Manufacturer Related Value-Based Contracts (VBC) – Working through "The Gnarly Details"

**FOLLOW A SYSTEMATIC APPROACH TO STAKEHOLDER ENGAGEMENT, REAL WORLD EVIDENCE &COMPLIANCE MANAGEMENT**

## Manufacturer – Stakeholder VBC Rules of Engagement Remain Unclear

U.S. bio, pharmaceutical and device manufacturers and their client base (medical providers, hospitals and health plans/payers) are held to complex, shifting and very high standards in terms of how they transact business. This requires them to proceed clearly and cautiously in terms of how they enter into buy-sell, pricing and contracting arrangements, as well as projects that implicate Safety & Medical Effectiveness and the exchange of confidential, regulated sets of data.

Solidifying these deals may require metrics extracted from Real World Evidence or other composite data sets, careful construction of incentives and considerations of the patient's personal factors, including compliance issues.[1] [2]

While regulators are interested in how the black-and-white pricing and financial terms work between the parties, they simultaneously promote less consistently understood concepts like "quality" and "value" as stated health care reform goals for contracts between payers and providers, including manufacturers. These ideas (by their nature) require the parties to work ever-closer together, gathering the facts, comparing treatment alternatives, and sharing results. *All the while,* steering clear of murky situations that could spell compliance disaster for their company.

[1] PharmaLetter. (2017, June 26). Value-based contracts require real-world evidence and patient support. Retrieved August 15, 2017, from https://www.thepharmaletter.com/article/value-based-contracts-require-real-world-evidence-and-patient-support

[2] Leonard, D. (2017, July 28). Value Depends on Real-World Evidence. Retrieved August 15, 2017, from http://www.ajpb.com/journals/ajpb/2017/ajpb_julyaugust2017/value-depends-on-realworld-evidence

To enable the parties, SME Health Systems has launched an affordable business framework that balances each party's need for compliance and control with the need for flexible and efficient interactions with key industry partners to share data and meet mutual objectives. The framework allows voluntary participation, provides HIPAA compliant standardized data sets across contract sites, catalogs project goals, terms and conditions, invoices, and communications.


**Parties Usually Talk Price--Not Value.** "Value" is a not typically part of the dialogue between Manufacturer, Payer, PBM or Provider, perhaps in part, because of subjective perspectives of what that means and how difficult it is to gain agreement. By contrast, "price" is a pretty straightforward discussion topic.

Although at this writing, U.S. health care reform is in a state of flux and arguably, crisis, few would argue that VBC is here to stay. The someone else who *actually pays* for health care beyond the patient (employer, private or public insurer, payer or risk-taking provider) has become more discerning about safety and medical effectiveness, including COST - effectiveness. Fortunately, because of transformative Health Information Technology (HIT) progress in provider and payer settings, the environment for value or risk-based contracting has dramatically improved access to missing pieces of "risk-share" or "value" data compared to 25 years ago.

*Zachary Hafner comments astutely, "Payers and providers have historically approached the economics of health care as a zero-sum game, where one can only win at the other's expense. Over time, this has translated to an unproductive focus on building scale for the sake of negotiating power rather than winning in the marketplace by increasing value for customers." He goes on to point out that creating shared incentives is hard work and often elusive, even for the partners with the best intentions.*

The highest impact VBCs in U.S. health care remain those between the payer and the health provider (including health systems and medical groups) as they play an endless game of "tug of war" over the same dollar for the care of a patient.

It's almost always zero-sum game[3]: For every dollar (even discounted dollars) allocated to a surgery, for example, the plan must disburse the cash it received under premium or ERISA programs. On the other side, for almost every dollar of revenue for a hospital or medical provider, there is a debit from the plan; discounts, adverse quality incentives or penalties all come from the same provider cash pool. Because of their respective revenue and margin pressures, plans and providers are not aligned except where they explicitly create shared incentives or penalties such as those associated with value based arrangements that shift some risk (and splits a reward) back to the provider.

[3] Hafner, Z. (2106, December 31). Beating the Zero-Sum Game, Together. Managed Care. Taken from: https://www.managedcaremag.com/archives/2016/12/beating-zero-sum-game-together on 08/14/2017

It may be even more difficult, then, for a manufacturer, not directly involved with the payer-provider financial ecosystem to engage in meaningful "value" discussions unless a framework for developing joint "skin in the game" projects is advanced. Without new ways to engage payers and providers, manufacturers remain stuck discussing "features & benefits", clinical indications and official FDA approved labeling, and, of course, the "price".

While studies are conducted pre-market approval to enable the value discussion, plans and providers often voice a stubborn skepticism regarding the Health Economics and Outcomes Research (HEOR) Studies conducted by a manufacturer, doubting that they will prove themselves out in their unique environment. Thus, they focus on product price and achievable rebates or discounts.

## The Value Statement Must Be Simple & Must Actually Get Delivered.

Manufacturers trying to market new products (especially high-cost biologics or products for specialty or orphan indications) in 2017 must create a very simple "Value Statement" that makes sense to all stakeholders (Payer and Provider alike), engaging in dialogue with each to consider the unseen obstacles to the product's adoption in the respective environment. It is certainly more complex that payer formulary and rebate contracting.

But it is also getting harder to actually deliver the message: Many, if not most, provider systems are restricting manufacturer access to specialists and staff. This means that value statement must be advanced increasingly through "alternative" channels, including tele-detailing and other outreach efforts.

> **"Pharmaceutical sales representatives are faced with increasingly limited access to physicians. According to ZS's latest research on physician access: 44% of physicians are considered accessible in 2017, compared to 47% in 2015, 51% in 2014, 55% in 2013 and 65% in 2012[4]."**

While a payer's coverage policy (including relative formulary status, specialty or retail distribution channel, and prior authorization rules) represents a critical bump in the road addressed through contracting, the prescriber's lack of awareness, adverse Electronic Prescribing positioning, and health system purchasing policy or personnel nuances may be even more important factors adversely impacting product uptake. These require local "boots on the ground" to understand and mitigate.

Local engagement can improve a manufacturer's understanding of the facts on the ground but can also enhance the provider's understanding of the merits of the product in a real-world clinical context. Legitimate projects that drive the collection of "Safety & Medical Effectiveness" data can enable development of "best medical practices" amongst alternatives, emphasizing those with greatest proven value. These goals are also promoted by the federal government and national quality advocacy organizations.

[4] AccessMonitor. (n.d.). Retrieved August 14, 2017, from https://www.zs.com/industries/pharmaceuticals-and-biotech/accessmonitor.aspx

Because of the complexity of the value discussion, a growing number of manufacturers are using field "Medical Affairs" teams to interact with health providers engaging in a more "scientific" or "clinical" exchange rather than one built simply around a sales result. They discuss things like care standards, disease management approaches, and potential opportunities for partnership. Manufacturers must remain within the approved indications labelling agreed to with the FDA, but the opportunity to have discourse about the value statement is at least possible with proper face-time.

### Getting to Successful VBC Requires Clearer Safe Harbors from CMS.

As we have previously illustrated in earlier white papers and presentations, a specific device or drug usually represents only a small component cost for the health plan or provider, making their interest in the value discussion of greater or lesser interest. For products with a price tag exceeding $10,000 per patient, however, the interest is likely to be much higher.

However, even if the value conversation is financially meaningful, lucid and attractive to the plan or provider, VBC can get tripped up on other critical challenges. Not the least of these relates to current manufacturer government pricing regulations and unclear government sanctioned rules of engagement or "safe harbors". Each company wants to keep out of legal and financial jeopardy due to these deals.

### Best Price.

In the U.S., drug and device manufacturers use well-established, but convoluted ways to offer differentiated prices to various parties including: a) discounted prices offered through charge-backs facilitated by wholesalers, prime vendors and group purchasing organizations for various possession-taking entities based on volume or trade category b) rebate payments made to health plans or pharmacy benefit managers, c) various other incentives offered to specific parties or classes of trade. These represent familiar challenges to manufacturer Government Pricing managers. While the regulations for calculating "Best Price", "Average Manufacturer Price" (AMP) or "Average Sales Price" (ASP) are complex and sometimes seem to evolve over time, they are ignored at one's own serious peril--for both the individual and the company. (See: Best Price Definition[5] )

Unanswered questions, even as CMS and health reform advocates are pressing the concept of VBC to include manufacturers' drug, biological, or devices, include these relating to Government Pricing & Best Price:

> How do payments made under a "Value Based Contract" impact Best Price and the calculation of AMP or ASP? What if the arrangement results in payments that could exceed the cost of the sale or the "best price" of the sale? Because VBC arrangements span many fiscal periods (potentially even years), how does this impact price reporting? Is there a safe harbor that would cap the impact of the payment so as to not financially destroy the manufacturer? At what level? Which parties are excluded or included for participation? What kind of provisions are permissible for Provider type entities to steer clear of other statutes, like anti-kickback provisions?

[5] Legal Information Institute. Cornell Law. Taken from URL on 08/14/2017. https://www.law.cornell.edu/cfr/text/42/447.505

### Sunshine Act for Transparency & Anti-Kickback Statutes to Combat Fraud.

Manufacturers are also required by federal law under the "Physician Payment Sunshine Act" to report any payments for any reason made to physicians or teaching hospitals so that this information can be transparently published to the public to disclose potential financial conflicts. Payments made in the process of collecting data necessary for considering or transacting a Value Based agreement could implicate the manufacturer's need to report, yet the payment may not go directly to a physician but to a hospital, plan or health care provider network. It is not clear how or whether VBC payments might implicate the Sunshine Act.

All parties are subject to serious penalties, including fines and imprisonment, for any infringement of "Anti-Kickback" rules which prohibit various activities that appear to be self-dealing at the cost of Medicare or other programs.

Tara O'Neill of the American Action Forum argues, "Federal anti-fraud policies, such as the Stark Law and Anti-Kickback Statute, complicate the ability of drug manufacturers to enter into value-based contracts with insurers and providers because such agreements may be viewed as inducing providers to prescribe a particular medicine. Congress and CMS should clarify and update these laws' safe harbor provisions to reflect the needs of the changing payment landscape.[6] "

### Most Value Contracts are Just Complex Rebate Arrangements

Current regulations may put manufacturers and their plan or provider partners at risk for being second-guessed after the fact about the goal of an agreement or associated payments.

Thus, manufacturers currently "thread the needle" with regard to government pricing and safe harbor payments so as to avoid either the appearance or fact of illegal or unethical practices. For this practical reason, they either enter into classic rebate contracts or provide price discounts that are "contingent" rebates based upon a data metric. This allows the VBC payment to factor into a GP calculation, rather than creating a true risk-share or creative contract terms that might jeopardize "best price". But it is not really a "risk-share" arrangement so much as a product discount scheme.

While the federal government and regulatory authorities, including CMS, have repeatedly expressed interest in advancing manufacturer participation in VBC that can demonstrate drug or device contributions to reduce the overall cost of care while improving quality and outcomes, they have not yet simplified the "rules of engagement." They are, however, openly expressing an interest to review the arrangement. In mid-2016, CMS offered the following guidance:

> "In response to specific requests from manufacturers as to how to reflect their VBP arrangements in calculating best price, CMS has concluded that the impact on a manufacturer's best price will differ depending on the structure of the VBP arrangement. CMS recommends that when manufacturers negotiate such arrangements with entities, they consult both the statute and implementing regulations regarding the determination of best price. In addition, CMS is available to address questions concerning a manufacturer's arrangement, if needed. CMS encourages manufacturers to submit any issues or questions to the CMCS Division of Pharmacy…[7]"

[6] Hayes, Tara O'Neill. "Current Impediments to Value-Based Pricing for Prescription Drugs." American Action Forum, 30 June 2017. Accessed 14 Aug. 2017.

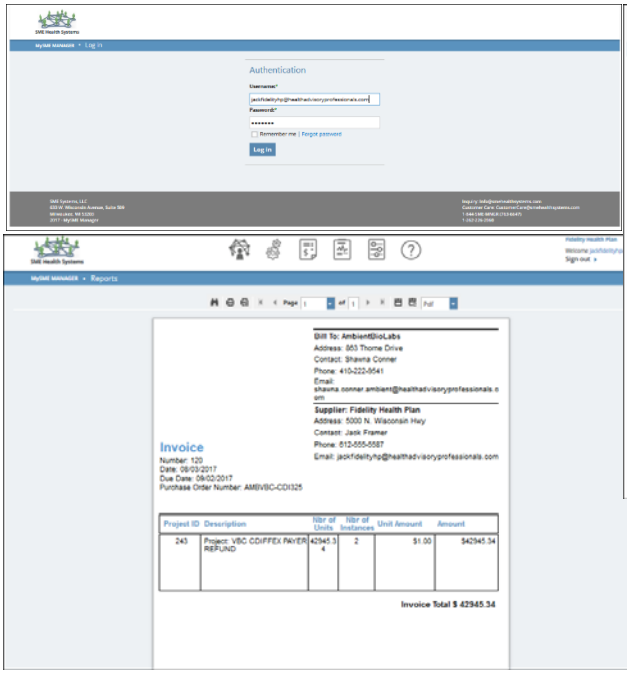
[7] State Release #176, CMS: https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf

Some analysts are calling for CMS to explicitly modify best price rules for VBC, and this author as well as others have called for manufacturers and potential VBC partners to include CMS in discussions, getting approvals in writing for any unusual creative terms and conditions as the regulatory guidance slowly comes forth[8].

## How to Proceed in the Midst of Some Ambiguity?

Start with the dialogue and the value statement. Between the manufacturer and the partner (health plan or provider entity), understand the perspectives, access to necessary data, and financial impediments. Construct a baseline, "pilot" phase to enable all parties to fully understand the numbers before engaging in the value or risk-based deal, under which the manufacturer sponsors the project and pays "Fair Market Value" fees for the staff time and materials in working through the data and details.

SME Health Systems has developed a framework to support business needs around Value Based Contracting for both the manufacturer (Project Sponsor) and payer or provider (as Project Partner).





The Safety & Medical Effectiveness projects are not limited to value based contracting but also include a large variety of other projects, including Medical Rebates, Operational or Administrative projects, Training, Patient Reported Outcomes, Longitudinal Registries, and self-conducted ERX validation projects.

Contact Terri Bernacchi at 262.893.9049 or Info@smehealthsystems.com for more information.

[8] Goldman, Dana. "Drop Medicaid 'best price' drug rules in favor of value-Based strategies." Modern Healthcare, 8 Nov. 2015. http://www.modernhealthcare.com/article/20151118/NEWS/151119888 Taken from the URL on 8/14/2017.