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**VALUE-BASED CONTRACTING**

**KEY CONSIDERATIONS FOR LIFE SCIENCES MANUFACTURERS**

In the following, Huron examines one aspect of value-based care—specifically, value-based contracting (VBC)—and the resulting implications for life sciences manufacturers. Elevating the trends and market events driving the increased focus on VBC, it becomes clear the time is now to address it in your life sciences organization through near-term action items across the commercial, R&D, IT, compliance, and GP functions.

The U.S. health care system is moving towards value-based care in an effort to curb rising healthcare expenditures. This paradigm shift continues to impact providers and payers through the introduction of pay-for-performance, bundled payment, clinical pathway, and other programs intended to replace traditional fee-for-service and volume-based delivery models.

More recently, biotech and pharmaceutical manufacturers made value-based solutions a particularly “hot topic,” as various stakeholders seek to apply an outcomes-driven approach to the pricing and payment of devices and therapeutics.

**Value-based Contracting: What is it, and why now?**

“Outcomes-based pricing” and “risk-sharing agreements” are common buzzwords in the life sciences industry lexicon. But the pace of change has been undeniably slow, so why is now the right time to actually do something about it?

Here, we define VBC as any contractual agreement between a manufacturer and payer in which the reimbursement of a therapeutic is tied to the clinical outcomes it provides in the real-world. Simply put, it is any contract that links whether, when or how much a payer pays for a drug to the actual safety and efficacy benefit it delivers in practice.

While the risk-sharing, rebate, and payment mechanisms of these contracts can be structured a variety of ways, they are all built upon the same fundamental premise of tying payments to real-world value.

Indeed, legitimate regulatory, legislative, and operational hurdles challenge the feasibility of implementing VBCs in the near-term. For example, the Office of Inspector General (OIG) has not issued sub-regulatory guidance on how such contracts should be considered from a risk-assessment standpoint.
There are also unresolved concerns as to how they impact government pricing and the calculation of Best Price. Actually executing these agreements at the provider level often requires both technology/IT infrastructure and sustained behavioral modification to ensure proper collection of outcomes data—a concept that often proves “easier said than done” in other applications.¹

However, several industry trends and events suggest that VBCs are gaining critical momentum and may be approaching a tipping point:

THE PUBLIC IS CALLING FOR IT.
Pharmaceutical prices remain the focus of intense public scrutiny, and have over the past 18 months—from the backlash surrounding both Valeant and Turing Pharmaceutical’s pricing approaches, to headlines criticizing Gilead’s $84,000 price tag for its novel (and curative) hepatitis C drug Sovaldi.

The debate also spills into public policy, with numerous U.S. presidential candidates explicitly calling out drug pricing reform as part of their 2016 campaign platform. While one could debate the merits and ethics of the U.S. pharmaceutical pricing system at length, the court of public opinion has made one thing clear: The onus is on manufacturers to prove the value of their innovations and justify the corresponding prices, or be called out publicly for it.

PAYERS ARE CALLING FOR IT.
Many therapeutic categories are growing more crowded with numerous products of limited clinical differentiation (e.g., the rheumatoid arthritis landscape). Many of these same categories face competition from cheaper generic or biosimilar entrants (again, RA).

At the same time, payers are eager to cut their specialty pharmaceutical costs by pitting relatively undifferentiated therapies against each other and selecting a preferred product in exchange for discounts or other contractual agreements—as was recently observed in the PBM contracting war between AbbVie and Gilead in the hepatitis C market. In these market conditions where access is an increasingly important basis of competition, innovative payer contracting approaches are critical points of differentiation.

IT’S ALREADY HERE.
A number of recent (and significant) agreements between payers and pharma manufacturers have turned VBC from myth to reality.

First, facing head-to-head competition for its PCSK9 therapy Repatha, Amgen locked in an exclusive pay-for-performance agreement with Harvard Pilgrim in which the payer can collect additional rebates if patients do not hit pre-specific cholesterol targets.⁵ More recently, Cigna & Aetna both announced VBCs for Novartis’ drug Entresto, linking rebate levels to the drug’s impact reducing hospitalizations for heart failure.⁶

Together, these trends make a compelling case that the industry has reached a breaking point, placing the imperative on manufacturers to explore VBCs and other novel ways to demonstrate the value of their products.

Innovative pharma companies are entering into these agreements today. And where challenges prohibit implementation, they are still actively
Today’s trial designs are thus critical to enabling VBC in the future, and these considerations should be integrated into R&D planning discussions to ensure alignment with all relevant stakeholders. For example, ask what endpoints, companion diagnostics, or data collection tools are going to be needed to support a post-launch VBC, and then consider whether current clinical plans accommodate those needs (or can be adjusted to do so).

3. COMMERCIAL ANALYTICS & IT

Assess what technology platforms or partnerships are needed to support VBCs from a data collection & analytics standpoint. Numerous technical hurdles and questions weigh down the feasibility of VBC... how can clinical data be reliably collected and analyzed to support a VBC between payers and manufacturers? Who will own, house and analyze the data? What level of EMR integration is required?

These are not simple questions to answer, and yet it is critical to evaluate them as prerequisite for VBC. If your current IT infrastructure is insufficient, the time is now to consider platform investments or novel partnerships.

4. COMPLIANCE

Define regulatory sign post events needed to pave the way for VBCs at your organization, and build relationships with the appropriate stakeholders. Undoubtedly, VBC poses compliance risk as the new world develops without clear guidance from OIG, and it is critical to understand and mitigate that risk.

Equally undeniably, VBCs are of growing strategic importance to your firm in our emerging market landscape. Don’t wait for
regulatory policy to catch up; partner with your contracting colleagues, understand current contractual arrangements and VBC ambitions, and define the critical regulatory scenarios and sign posts needed to make VBC a reality. Make the call today.

5. GOVERNMENT PRICING

Map out the implications of a VBC on Government Pricing calculations, and anticipate potential statutory amendments addressing VBC arrangements. Currently, VBCs affect numerous price calculations including Best Price, ASP, and AMP, and has potential implications on Bona fide service fee (BFSF), Fair Market Value (FMV), free good exclusion requirements, lagged price concessions, and bundled arrangements. Learn and communicate these implications within your organization. Additionally, keep close watch on potential statutory amendments like those called for by Lilly & Anthem,¹ and develop a response plan so that you can be ready if/when they are implemented.

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Conclusion

It is the imperative of innovative pharma companies to demonstrate the value of their products to meet stakeholder demands and differentiate in an increasingly competitive marketplace. The opportunity (and challenge) to develop and implement these contracts lies beyond the scope of just traditional market access and contracting functions, however.

No matter your company or function, there are things you can do today to prepare for a VBC future to create a sustainable source of competitive differentiation for your organization, and more importantly, to demonstrate the life-changing benefit the therapies provide in the real world to patients.