

A REALITY CHECK: U.S. MANUFACTURER-RELATED “VALUE- BASED”, OUTCOMES OR RISK- SHARING CONTRACTS

Where
Health
Partner
Perspectives
and
Incentives,
Regulations,
Workload
and Data
Meet Reality
Head On



Lessons Learned Along the
Rocky Path to Success

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A Reality Check: U.S. Manufacturer-Related “Value-Based”, Outcomes or Risk-Sharing Contracts

LESSONS LEARNED ALONG THE ROCKY PATH TO SUCCESS

Manufacturer Value-Based Contracts with Payers or Providers Remain Rare & Elusive

In the six years since the passing of the Affordable Care Act which architected stepwise changes away from the traditional U.S. “Fee-for-Service” (FFS) model toward a “Value-Based” (VB) payment system that compensates providers on the basis of “results” over efforts, much has been written by health care experts about how these changes will drive quality, contain costs, and improve health. Many have also extended the broad adoption of these methodologies to the realm of pharmaceutical or device products. The search for “value”, defined as a measurable outcome per dollar of cost, is the fundamental basis for these efforts¹.

This contracting methodology for branded products has been slow to develop over the past six years for a number of practical reasons.

Chief among them are 1) an inhospitable legal environment with potentially catastrophic downside risk to the manufacturer, 2) inaccessible population, patient and claims data and 3) poorly defined outcome metrics that define the payment terms between the parties. So, while it is easy to find articles

and blogs regarding the “Best Practices” relating to these deals, the deals themselves are very few in number and far more “art” than “science”, offering more “lessons learned” than “best practices”.


$$\text{Value} = \frac{\text{Outcome}}{\$ \text{Cost}}$$



“The Wall Street Journal reported last month that payers and PBMs have reached at least a dozen “value-based” or “at-risk” deals with manufacturers since 2014. These contracts bring higher payment rates for improving patient outcomes, supplanting traditional contracts in which payment brings rebates based on volume and the right place on the formulary.”

Theoretically, value-based or “at-risk” agreements are a positive development. However, because these contracts are still based on rudimentary volumetric math, they are little more than value-based window dressing. As the only drug on formulary within these agreements, manufacturers are still banking on a simple volumetric percentage of efficacy to meet payment and profit goals. Real improvements in outcomes and value-based contracts require more lifestyle factor measurement and corresponding agreement on their evaluation.....

Moreover, “Alan Lotvin, executive vice president for specialty pharmacy at CVS, said the setups can be difficult to execute because many achievements—such as a reduction in heart attacks and deaths for cholesterol drugs—can take years to become clear, and patients may be impossible to track over time as they change insurers and jobs.” O’Connor, M. Managed Healthcare Executive

¹ Porter, M. E. (2010). What Is Value in Health Care? *New England Journal of Medicine N Engl J Med*, 363(26), 2477-2481. doi:10.1056/nejmp1011024

As of this June (2016), in the U.S., the documented number of agreements are in the “dozens”, though the exact number is not known as these are private contracts between private parties². Worldwide, where product pricing is more heavily regulated by the state, but where the political environment has fewer concrete obstacles to these agreements, they are also small in number. Consultants have estimated that there are fewer than several hundred worldwide to date, and many of them are not mature enough to reach definitive conclusions about their effectiveness.

The agreements may contain any variety of terms and incentives between a manufacturer on one side and a payer or provider on the other side: 1) **Price Discounts** incorporating components of traditional product discounts off of a listed price (either at purchase or as a rebate), 2) **Conditional Discounts** with retrospective payments made under terms agreed to by both sides that meet objectively measured metrics or 3) **Value-Based** arrangements that require complex provisions for how to measure value and apply reward. Many health plans and manufacturers express strong interest in entering into these deals, but most have been difficult to initiate. Actually implementing and administrating them is an even greater challenge!

“...these agreements and the projects around them would be more successful if they were cultivated and launched in a different manner.

Using small projects, performed on a “Fair Market Value” basis, the parties can start with a more informed baseline from which success factors can be devised to mutual satisfaction, with neither side assuming excessive risk.”

SME Health Systems

This paper is intended to orient the reader to the current reality of agreements / contracts variously characterized as “Outcomes”, “Value-Based³” or “Risk-Sharing” between manufacturers and hospital systems/providers or health plans. These arrangements have been promoted by health policy advisors as a means to achieve better health outcomes per drug or device dollar spent. As founders of SME Health Systems and seasoned healthcare executives, the authors believe that these agreements and the projects around them would be more successful if they were cultivated and launched in a different manner. By using small projects, performed on a “Fair Market Value⁴” basis, the parties can start with a more informed baseline

from which success factors can be devised to mutual satisfaction, with neither side assuming excessive risk.

It’s Harder than it Sounds. Even if most payers, providers and manufacturers continue to want these new deals, hoping they bring significant value to their organizations, the contract methodologies must be able to overcome stubborn obstacles that have prevented their adoption and propagation throughout the

² O’Connor, M. (2016, June 1). Four critical components for successful, value-based pharma contracts. Managed Healthcare Executive. Retrieved July 29, 2016, from <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/four-critical-components-successful-value-based-pharma-contracts>.

³ Deloitte defines VBC as follows: “Under value-based pricing agreements, payers and pharma companies agree to link payment for a medicine to value achieved, rather than volume. These Agreements dictate price (and/or coverage) relative to actual (i.e., observed in real-world) performance.” Deloitte Center for Health Solutions.

Issue Brief: Value-based pricing for pharmaceuticals ... (n.d.). Retrieved August 8, 2016, from <http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf>

⁴ ““Fair market value” is a legal term that tries to define the appropriateness of payments when there are conflicting or at least multiple justifications for those payments. FMV turns up in many business transactions, but specifically in payments occurring where government funds are involved. FMV in the pharma industry can affect contracts between trading partners (when the ultimate payor is CMS), or in physician-manufacturer relationships where physicians can be both advisors and clients. This article will focus on the latter situations.” Defending Fair Market Value (FMV) Assessments. (2010). Retrieved August 08, 2016, from <http://pharmaceuticalcommerce.com/legal-regulatory/defending-fair-market-value-fmv-assessments/>

marketplace. Once these are addressed, the fulfillment of the key promises ----e.g. demonstrating greater patient adherence, lower costs of care, and improved outcomes⁵ can occur. A few of the higher impact barriers are listed below:

- **The legalities.** Because there is no “safe harbor” spelled out for these arrangements by regulators, there are currently practical limitations on the ability of manufacturers to collaborate with payers or providers on these pioneering contracts⁶.
 - **Best Price & Anti-Kickback Concerns⁷.** Pharma and Device companies cannot afford to “run afoul of anti-kickback laws (state and federal) or Medicaid best price law and Medicare Part D regulations. If a pharma company lowers price to a commercial customer, they also must lower price to the government programs”⁸. Breaking best price can create a catastrophic financial cost cascade to the manufacturer such that any contract that threatens a new Best Price is not feasible. Moreover, both sides must assure that project and contract goals and associated payments establish a clear and reasonable benefit that avoids all legal and appearance concerns regarding inducements or kickbacks. Until the federal government endorses regulatory guidance for the “safe harbors” around these concerns, some parties will stay in a holding pattern regarding these arrangements.

“...policymakers to date have failed to recognize that the principal reasons value-based pricing has not taken hold in both commercial and government markets are the Medicaid and Medicare programs’ legal and regulatory structures. More specifically, application of “Best Price” principles (in Medicaid and 340B) and Medicare Part B “Average Sales Price” (or ASP) requirements as they are currently constructed create an artificial floor prohibiting true innovation in drug pricing. And until regulators acknowledge this floor, and address it, value-based pricing is unlikely to expand in the United States market.”

All Foam, No Beer: Broad Uptake of Value-Based Pricing for Prescription Drugs Unlikely Without Serious Legislative Change. Farber, David, et al.



- **Appetite for Risk.** In a sense, these deals generate a “risk” equation between the parties under which there is an identifiable, quantifiable financial risk to be shared. While both sides hope for a win-win scenario at the outset of the contract, future risk is not entirely “knowable” and one party may lose more than they calculated⁹. A manufacturer, for example, is not typically able to offset the full cost of hospitalizations due to

⁵ Insurers, drugmakers wrestle with how to build win-win value-based contracts. (n.d.). Retrieved August 08, 2016, from <http://www.modernhealthcare.com/article/20160220/MAGAZINE/302209963>

⁶ Farber, et al. Pharmaceutical Law & Industry Report. (n.d.). Retrieved August 8, 2016, from http://www.kslaw.com/imageserver/KSPublic/library/publication/2016articles/3-4-2016_Bloomberg_BNA.pdf

⁷ The federal Anti-Kickback Statute (“Anti-Kickback Statute”) is a criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business. See 42 U.S.C. § 1320a-7b. Health Law Resources. (n.d.). Retrieved August 08, 2016, from [https://www.healthlawyers.org/hlresources/Health Law Wiki/Anti-Kickback Statute.aspx](https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx)

⁸ Berndt ER, Newhouse JP. Pricing and Reimbursement in U.S. Pharmaceutical Markets. HKS Faculty Research Working Paper Series. 2010 Sept;RWP10-039.

⁹ Insurers, drugmakers wrestle with how to build win-win value-based contracts. (n.d.). Retrieved August 08, 2016, from <http://www.modernhealthcare.com/article/20160220/MAGAZINE/302209963>

unforeseen factors outside its control. Unless crafted carefully, if an agreement results in a product failing to meet metrics, the manufacturer (which still has its own “fixed operating costs” that it must cover) cannot afford any impact that eliminates its margin and forces it out of the market. Instead, the parties must create a realistic and transparent environment that allows visibility into gains and losses with an understanding of the fiscal impact of the deal on each side. To enter into a deal, without a cap and clarity of terms, may create future costly disputes between the parties and long term ill-will.

- **Alignment of process and work incentives.** One of the big practical challenges with these agreements is how the companies and the project teams beneath them are motivated (or not motivated) to fulfill specific requirements. If the parties are simply working for a deeper-discount on a product, earned by the provider or plan’s supply of data and the measurement of metrics, the deal may be a relatively easy exercise in gathering data from various systems and subsystems. However, particularly for contracts that endeavor to illustrate comparative effectiveness or to share in upside based upon a change in process, the success of the agreement or project involves actions to be adopted by teams on the provider or payer side. In this case, team members must be motivated to something other than “passive” participation.

- **Physician & Clinician Behaviors.** Are the parties working with the patient aware of the project or contract’s existence? If the results of the agreement requires employed or contracted physician involvement, how is it driven? If success with the agreement requires the fostering of a new behavior aimed at meeting the metrics (whether financial, quality, or satisfaction related), is there sufficient recoupment of costs incurred by the staff of the facility or plan? These efforts on the part of personnel or a change in their entrenched processes may themselves represent costs to the provider or payer that should be part of the contract. One element of the provider’s deal analysis should be addressing the tough question, “If we are reaping \$X benefit, did it cost us \$X + to achieve?”

- **Health Plan versus Provider.** Typically the party that drives patient care decisions and can impede the success of these agreements is not the same party that develops payment policy or holds financial risk for the payment for the product.

- **Who Has Risk?** The transfer of risk from health plan (as payer) to provider (hospital system, physician, pharmacy) is the basis for the current U.S. system: if the Payer won’t pay, the provider won’t order/prescribe/dispense unless the patient is okay with paying the full amount. However, the plan/payer does not typically generate the prescription except as through this process by denying or complicating the coverage of another option. Understanding who generates the product order is a key necessity to the success or failure of these novel agreements.
- **Disincentives May Be a Larger Factor.** Often the pre-existing payment agreements between a payer and its contracted provider will not align with a manufacturer-to-plan outcomes contract. To illustrate, if the plan reaps the savings or a deeper



discount, how is any benefit transferred to the provider (hospital or physician)? Does the agreement require the provider’s contribution or cooperation in order to be successful? Failure to understand incentives at the payer, provider and even patient levels can spell failure for these specialized agreements. At a minimum, disincentives for cooperation need to be understood and minimized before the deal is inked.

- **Navigating Already Rough Waters.** Another factor that cannot be overlooked: the relationship between the payer and provider or physician and hospital system may be contentious for legitimate reasons as they argue routinely about fees, withholds, and quality bonuses. When the agreement requires them to cooperate and share their medical, EMR, or pharmacy data, just managing the conflicts and personalities adds challenge to the process!
- **Project Costs.** As described above, the outcomes or pricing arrangements must be of enough value to overcome the costs of implementation which may include, for example, additional patient monitoring or utilization data extractions. The costs must be less than the gain. Manufacturers should be prepared to carve out and cover the cost of administering and managing the work involved in the agreement away from product discounts or other incentives.
- **Data & “Real World Evidence”.** Unfortunately, the necessary data used to provide the baseline metrics and establish achievement toward a mutually defined performance goal does not always reside in efficiently accessible places. Depending on the goal of the contract, data may be required from various non-contiguous databases: at the payer, the pharmacy benefit manager, the hospital, outpatient settings, including the physician office and all care providers or even from the patient (as Patient Reported Outcomes). The data is needed to track and calculate contract performance, and to assure payment accuracy. The data and infrastructure which maintains it often represents a significant obstacle for the administration of these agreements. Some disease states or product propositions may require relatively few metrics (e.g., the achievement of an average lab

value) to be gathered from these data in order to establish success while others may require years of data to be gathered and very complex analytics.

The anticipated growth curve of these deals. Until the U.S. regulatory picture is officially clarified, it is hard to believe that these agreements will multiply considerably, even with the technical and process challenges resolving over time. ZS Associates anticipates a gradual evolution unfolding in a cautious market place.¹⁰

All that said, these contracts are something that manufacturers should anticipate because

“We anticipate that the ultimate inclusion of pharmaceuticals in value-based payments systems will result from a cautious market evolution. The success of legislative and regulatory changes that are required is uncertain, especially given the contentious political environment in the U.S.

Similarly, we anticipate that both payers and manufacturers will cautiously adopt these new payment models, especially given the logistical barriers of measuring the health outcomes that these contracts require.” ZS Associates

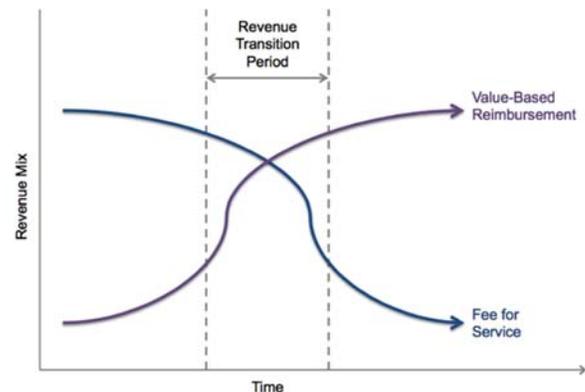
¹⁰ Transitioning Pharma to Value-Based Payments Will Require More Than Corporate Collaboration. (n.d.). Retrieved August 08, 2016, from <http://info.zsassociates.com/activeingredient/transitioning-pharma-to-value-based-payments-will-require-more-than-corporate-collaboration>

providers (who directly choose or impose influence on which product to use) are seeing their financial incentives change toward cost accountability. This is especially true for drugs or devices that cost many thousands of dollars to the plan (e.g., hepatitis C, oncology, PCSK9, specialty medications). Many consultants recommend that the manufacturer takes the initiative---now---and thereby better understand the levers within payer or provider organizations. Manufacturers must prepare their organizations for customers that respond to product costs very differently due to their own new constraints within a value-based payment system, in an environment that is almost the polar opposite of the past. Manufacturers choosing to delay engagement could see their competition entrenched, leaving them out in the cold.

Stakeholders from individual physicians to large organized customers like integrated delivery systems or medical groups are increasingly thinking in terms of “value” for health outcomes for high-impact disease states. However, the impact on them for any given product may be negligible (not enough for them to care) or may be shifted elsewhere. For example, the manufacturer may not realize that the physician has no financial accountability for the use of specific drugs or devices and can order them without restriction. The financial risk for their use goes entirely to the hospital or to the payer. Perhaps a product is wide open for use but is absent from the physician’s electronic prescribing system. The manufacturer should consider not only the payer or the ERX vendor in its activities, but the full context in which the clinician makes product selection decisions.

A handful of companies have claimed success in using these agreements to differentiate their product from alternative options by showing better health outcomes, such as the classic “reduced mortality rate” or “fewer readmissions to the hospital”. Unfortunately, depending on the drug category and the promise, these benefits may not be realized until years out in the future, when the parties signing the deal have long since retired and the patients have moved on to a different health plan. Shorter term value propositions are easier to address.

The Provider’s Environment is Undergoing a Massive Overhaul. Most hospital systems, medical practices, and outpatient facilities remain dependent upon fee-for-service activities. Acting logically, they must continue to maximize census profitably, generating services or procedures for fees that cover costs. Medical groups still need to see patients to treat illnesses, coding the encounter and submitting a bill for payment. Health plans continue to collect insurance premiums for underwritten benefits. The predominant payer revenue contracts in place at a provider always drives the behavior of clinical teams which tend to treat all patients the same way regardless of payer incentives that may not be known to them¹¹.



PROVIDERS TRANSITION WILL OCCUR OVER TIME

As value or accountability-based practice patterns start to shift that balance in the next couple of years, clinician behaviors will change. When a greater percent of patients managed by a specific health care system or practice is paid under a risk-contract, managing costs will drive provider compensation and have a greater relationship to performance goals. Currently, under a bonus-for-results system, the time

¹¹ Health Catalyst The Key to Transitioning from Fee for Service to Value-based Reimbursement. (Diagram)
<https://www.healthcatalyst.com/hospital-transitioning-fee-for-service-value-based-reimbursements>

between a treatment decision and the impact of any bonus gain or reduction remains far removed and may have a blunted behavior impact. However, evolving clinical pathways and more interactive Electronic Medical Records and Electronic Prescribing systems may result in a more consistent prescriber decision-impact where goals of the VB contract could be applied, improving contract results.

Both Manufacturers & Providers/Payers Need to Reorient Their Organizations to Each Other

Different Priorities. As just described, the manufacturer and Provider/Payer do not rank priorities in the same way. The product that is so profoundly important to the manufacturer may represent only a negligible cost to the provider or plan, generating very little interest on its own. Traditionally, manufacturers have used sales representatives to drive awareness and prescribing at the physician or hospital level.

A hospital's labor spend “typically eats up the largest chunk of a hospital's operating revenue, and since 2006, labor costs have absorbed 50 percent of revenue on average.”

For a provider, in other words, labor time is money.

The physician or hospital may literally “not care” about a product. They may care only about acquiring it at as low a cost as possible, typically purchased at the Group Purchasing Organization’s (GPO) discounted rate. Hospitals don’t want to add expensive drugs or devices to the cost of hospitalization unless they have a proven benefit to the whole cost of hospitalization because they are usually paid a flat fee per admission....and that drug or device literally comes out of their own pocket. Their incentives may flip for outpatient procedures and visits because the fee schedules may actually create a more attractive revenue opportunity.

Uniformly, what they do care about is the cost of and access to expert labor and effective tools of treatment. A hospital’s labor spend “typically eats up the largest chunk of a hospital's operating revenue, and since 2006, labor costs have absorbed 50 percent of revenue on average.¹²” For a provider, in other words, labor time is money. Most products are secondary and will be avoided unless value is proven to offset costs or if the burden is shifted to another party.

Executives within the IDN/Hospital System and payer sides have noted their interest in engaging in forward-leaning Value-based or outcomes contracts but given the labor-cost conundrum above do not want to adopt initiatives that require time or materials without consistent and offsetting revenue.



Stimulated by health care reform factors, leaders within these organizations have significantly shifted their financial focus away from just getting revenue and much more heavily on managing costs. They have taken on significant new head count associated with new requirements (e.g., address mandatory quality reporting and regulatory requirements, demanding and aging patient populations, protocol adherence) at the very time they are contending with lower payment rates and new

¹² 10 Statistics on Hospital Labor Costs as a Percentage of Operating Revenue. (n.d.). Retrieved August 08, 2016, from <http://www.beckershospitalreview.com/finance/10-statistics-on-hospital-labor-costs-as-a-percentage-of-operating-revenue.html>

penalties. They are more often seeking ways to either cover costs or cut them, often expressing a specific awareness of the cost (and opportunity) around drugs, especially specialty products.

Choosing the Best Value-Based Contract Partner. You can't work with everyone in every market at this point, so you will want to target entities that meet objective criteria tailored to your organization's capabilities. Not all manufacturers will make a good contract partner for the payer/provider; and from the manufacturer's perspective, not all payers or providers will be able to fulfill expectations for these deals. For each side, in order to be a good partner, the parties must have 1) properly aligned financial incentives, 2) top-quality and motivated team members, 3) an ability to access, extract and/or analyze the right sets of data, and 4) commitment to hold disciplined project meetings to assess performance along the way. Some organizations can be ruled out at the outset.

Time-Driven Fiscal Incentives Often Drive a Focus on Price over Value. To a greater degree than payers, hospital systems or providers, pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) are more focused on the manufacturer's product price (with achievable discounts) and utilization volume than its longer term value. They seek discounts to pass along to their constituents and hope to mitigate unpredictability regarding price; their incentives are geared toward short-term costs (usually in one year cycles). This short term price-focused vision is due to their business models and contracting cycles. It may also mean that it will be more difficult to generate a true value-based agreement with PBMs or GPOs without clear involvement of the payer or provider entity.



- **Multi-Year vs. Single Year.** For that reason, in order to generate interest in longer-term, value-based or outcomes contracts, manufacturers must consider the practical difficulties of value (Outcomes/Cost) measured in multi-year terms with single-year focused organizations.
- **Payers.** Health plans (payers) typically price their own offerings in terms of one-year underwriting cycles; value-based agreements that reward performance within a one or two year cycle are most likely to be of interest to the payer. Beyond that, because members are likely to move to another health plan, longer term payoffs are more difficult to conduct or justify, in part, because the cost may occur in the first year but the benefit is spread over many, after the member has moved on. While they (like the PBMs and GPOs) are likely to want access to a deeply discounted product price, they may be willing to use the higher priced product if there is evidence of cost-offsetting value that justifies its use. These kinds of plans may make good VB contract partners.
- **Hospital Systems/ IDNs / Physician Groups.** By contrast, hospitals and medical providers are variably motivated by product price or discounts. They will consider the impact of the product cost on themselves versus another party. Unlike the plans or PBMs, they are more likely to retain patient loyalty and want to maintain longer term treatment local patient relationships. Although the financial benefit of an outcomes contract is typically managed between a payer and the manufacturer, the medical provider or hospital system plays an indisputable role in its success. The contract will typically leverage performance metrics based on a captured population, underwritten by a specific payer and/or managed by a specific provider facility or system. Thus, the provider role is critical.

- **Manufacturer Focus.** Manufacturers are financially incented to increase sales, maximize profitability, and build market volume and share for shareholders, while keeping all kinds of risk to a minimum. From discovery to patent protection loss, this means getting a product to market and meeting the launch plan. The manufacturer must be able to convince an always-skeptical medical professional that the product (drug or device) possesses merit which makes it useful to them or their patient. Like all businesses, manufacturers are also incented in single year financial reporting cycles. However, in order to justify the product price (which involves years of effort and millions of dollars consumed in getting to market) manufacturers may want to offer “warrantees” or assurances that the product has demonstrable value over alternatives by offering a Value-Based or outcomes contract. Manufacturers also invest in Health Economics and Outcomes Research and other vehicles to tell the “value” part of the product story. Especially with a very highly priced product, the company must be able to clearly define the return-on-cost, sometimes facing restrictive coverage and reimbursement terms. Engagement with payers or providers (whether via contracts or otherwise) must steer clear of trouble with regulators or laws relating to the Anti-Kickback Statute and “Best Price” provisions.

Start with Small FMV Projects. In addition to paving the way for strategic outcomes – or value-based contracts, paid FMV manufacturer projects can enable the hospital system/payer or provider to offset operational costs tied to the project, often underwriting some of the costs of the same staff responsible for driving quality and data reporting initiatives.



Because of this, and because today’s physicians are more often system employees rather than independent entities with privileges at the hospital, these projects represent an attractive means for them to engage the manufacturer around interesting and relevant clinical issues focused on safety or medical effectiveness. The process and staff time involved with visiting with the manufacturer’s representative, evaluating the project and/or product, negotiating and engaging a VB contract, and finally, gathering and assessing data represents a significant cost to the plan or provider. More and more health plans and

providers/hospital systems are restricting manufacturer access to employees to eliminate that cost impact; without a clinically or operationally relevant project to engage them, they may simply decline the manufacturer relationship.

These level-setting projects should be engaged BEFORE the proposal and execution phase of any outcomes, shared-risk or value-based contractual arrangement to assure feasibility and to evaluate baseline metrics. These small Assessment Phase projects enable both sides to weigh the opportunity for an engagement more clearly and compensate the system for the FMV cost of its time, removing the most obvious objection to collaboration.

Flush Out the “Three C’s” Before a Deal is Inked. The “fit” between the parties is an essential success factor that can be considered in several areas. Each side needs to understand the “Context” of the other, the “Costs” as it impacts each organization, and whether the “Choice” to use the

product represents an uphill battle or an obvious option for clinical use to understand the effort necessary.

Context. The manufacturer does not always understand the perspective of the prescribing healthcare professional or system decision maker as it relates to the use of its products. Nor is the manufacturer’s perspective always obvious. Each side should share what is on their own “go-no go” checklist for moving ahead with a FMV Project and/or a Value-Based Contract. The criteria will vary from one provider/payer to another; from one manufacturer to another.

Both organizations must understand the expectations of their internal management teams, the Rules of Engagement, the need for timely and accurate data, and how they will provide governance to the project. Part of the “context” exercise involves understanding the way things work, especially within the payer, hospital system, or provider group.

- Medical Systems & Subsystems.
- Physician & Clinical Managers.
- Payer Mix.
- Technology & Data Extraction Capability.
- Degree of Interest in Interacting.
- Financial Drivers.
- Access to Data Variables.
- Product “Point of Selection”.
- Reimbursement / Coverage Hurdles.
- “Clinical Pathways” & Treatment Protocols.
- Patient demographics.

Costs. Neither the manufacturer nor the payer/provider/hospital system wants to find out at some point into the life of the VB agreement that costs associated with the deal have exceeded projections and that the project is “taking on water”.

For that reason, during the FMV project baseline Assessment Phase, the parties should understand how the product cost impacts the prescriber or hospital, financially. Does it impact employee medical staff in a different way than independent physician groups? Does the provider stand to gain or lose by the selection of the product? Who is the product selection decision maker? If an agreement requires staff time to fulfill, is the upside of the agreement enough to offset the costs of people, processes, products, and indirect expenses? Does the “upside” go to the right parties in order to fulfill the value story hypothesis? Who are the predominant payers impacting the providers/prescribers under consideration? How does the payer’s coverage policy impact the provider?



One of the most challenging aspects of health care has been quoted a number of times regarding the provider’s own understanding of cost: “... A fundamental and largely unrecognized problem: We don’t know what it costs to deliver health care to individual patients, much less how those costs compare to the

outcomes achieved. Understanding costs could be the single most powerful lever to transform the value of health care¹³.”

Choice. Does the product stand on its own merit and have an “already-understood” benefit to the patient, physician, or system? In other words, how hard will it be to convince the clinical decision maker of the integrity of the product’s value proposition? How high is the hurdle for the product within the partner’s community? More data and a longer “value proof” term may be necessary if the value proposition is not obvious. If the value proposition is obvious, then it may fall to an agreement based on more traditional price discounts and/or minimal effort to encourage selection.

Ten Key Lessons Learned for Both Sides: Although there are a small number of complex, value-based deals in place in the U.S. market and “best practices” are probably left for discussion in a future white paper, there are some simple practices that the parties on both sides should consider based on already-obvious situations. Once you have chosen whom you want to work with, you can adopt the following recommendations to maximize the chance for successful engagements.

1. **Planning Discipline & Project Organization Will Impact Achievement.** Signing a deal involves a significant commitment by the parties on both sides. Before the agreement is inked, a limited Assessment Phase project will help to lay out the foundations. This project lays a foundation for mutually agreed, sound metrics, access to data, reasonable timelines and team familiarity. Poor execution is often directly attributable to poor planning or not enough information at the outset.
2. **Proceed with Caution, but Be Optimistic.** Start with baby steps to understand personalities, risks, parameters, costs, and context. Manufacturers should get to know the local players by first proposing this Assessment Phase, involving “fair-market-value” payments to reimburse for time and materials. Both parties will want to gather the facts during this process to lay a good foundation moving forward. Team rapport is critical.
3. **Manage Expectations Inside Your Organizations.** The kinds FMV assessment projects that lay the groundwork for larger value-based deals should probe the context of disease state management and product selection, considering how results are to be evaluated. These risk-based contracts rely on data often labeled “real-world evidence”. Remind colleagues that these data are not generated with the same rigors of precision as a Randomized Clinical Trial (RCT). They do not (by their nature) match the RCT’s need for participant randomization, exclusion or inclusion criteria, researcher blinding and compliance, and data collection. It is important that both the manufacturer and the provider/payer understand these differences and convey them to internal teams to manage expectations. These are not necessarily IRB managed engagements, for example, but they may include some of the same team members as the IRB.
4. **Don’t Assume all Systems/Providers (or Manufacturers) are Alike.** During the Assessment Phase, clarify local interdependencies between providers (Medical Groups) or hospital systems to comprehend the context of product use, as well as financial and economic drivers for the individual clinician, patient or population. One often overlooked element is how primary care-to-specialist referral patterns work. This is particularly important in disease states managed by specialties like orthopedics, cardiology, neurology, and oncology.

¹³ What's New? (n.d.). Retrieved August 10, 2016, from <http://www.nhha.org/whats-new/297-ny-times-why-medical-bills-are-a-mystery> attributed to Robert S. Kaplan and Michael E. Porter The New York Times, April 14, 2012

5. **Parties Should Agree on Metrics for Success and Milestones.** Over the course of the Assessment Phase/FMV Project, the parties can agree to deal-related performance metrics and the data points that will be used to determine payouts and success factors. Key to this is determining the population covered, the primary and secondary data sources, timeframes and applicable calculations.



6. **Define the Data Gathering**

Process. Understanding and agreeing to the milestones and performance metrics does not mean that the ability to actually extract the data has been resolved. The parties (typically the payer, the provider/prescriber or hospital system) must assume responsibility for HIPAA compliant extraction of the requisite data points on a timely basis in order to support the agreement. Most agreements will require some mix of claims data, including payment and cost terms, EMR fields (lab or clinical values), patient reported outcomes and impressions and business context with other product options.

7. **Communicate Regularly to All Parties Impacting Success.** Once the Assessment Phase is underway or if you have determined to go ahead with a Value-Based contract, be certain to hold regularly scheduled meetings to inform the team about progress. As obstacles are identified, this team may be able to remove them; if costs are an issue, transparency early on will help identify resources or redirect efforts. Often these agreements require executive oversight; meeting documentation and interim results reporting assures that governance is pro-active rather than re-active.

8. **Build Out Your Teams.** The talent assigned to the project or deal may be its single most important success factor. Most organizations find competent team members with leadership skills are in short supply. Both sides require organized and experienced clinical and business teams in order to complete the Assessment Phase and move on into Value-Based Contract implementation. This is where the manufacturer’s support can make a key difference.

- While they probably have a team of their own experts, manufacturers should consider tapping into firms like The Medical Affairs Company in order to affordably augment their own Medical Science Liaisons and Key Account Managers to support these projects. (See <http://www.themedicalaffairscompany.com>) These resources can organize and support the meeting process, chronicle results and clarify the metrics.
- On the other side, payer, health system/provider team members are typically experienced nurses or clinicians with an understanding of Electronic Medical Records systems, and the workings of the health system itself. They typically have an understanding of quality metrics, regulatory reporting, and may have a research background. They operate under the organization’s rules of engagement which governs their roles and can coordinate project participation with medical and administrative staff decision makers. This entire process may be aligned in some way with the Institutional Review Board (IRB).
- Most providers/hospital systems will expect FMV compensation for the time and materials associated with these deals and projects, including meeting time and materials.

9. **Keep It All As Simple as Possible.** These agreements can only work when both parties understand the rules, metrics & milestones and can quantify what is at stake. If you cannot explain the goal in a paragraph or two, it’s too complicated. There should be a consensus

between the parties as to what you are trying to achieve. While there is no regulation or legal requirement that restricts or thwarts these successful arrangements, the FMV projects and Value-Based deal should generate a paper trail that allows executive review and assures compliance.

10. **Meaningful Engagement is NOT a Sales Pitch.** When the parties are working collaboratively in the Assessment Phase or thereafter, under a VB contract, they become familiar with each other, securing mutual trust. While manufacturers have an obvious need to sell product, they should operate within the rules of engagement agreed-to with the hospital system / payer /provider or merit long term damage to the relationship.

SME Health Systems’ Novel Framework. SME Health Systems has developed an engagement framework (MySME Manager™) that will advance these kinds of projects by interested manufacturers and interested provider entities. MySME Manager™ addresses both tactical and strategic needs for both sides.

FMV Projects may be related to operational needs (e.g., project meetings, training sessions), the gathering of “Real World Evidence” (RWE), tracking patient outcomes or registries, “Risk Evaluation & Mitigation Strategies” (REMS), or providing the basis for value-based agreements, supporting both the Assessment Phase and continued data gathering during VB contract implementation. Each project generates a custom-project data set that pulls data from potentially hundreds of different sites in a homogenous, consistent way. The system provides homogenous data and a FMV billing invoice.

Why SME? The MySME Manager™ Framework provides both sides with a variety of cost-effective components that support changing collaborative relationships. Both sides are interested in these projects because they:

1. Change the nature of the relationship between manufacturers and health systems /providers/ payers from simply “sales” to “collaboration”, especially within closed systems.
2. Allow both parties compliant access to valuable & objective “Real World Evidence (RWE)” on the use of various products, disease states, and clinical metrics which can advance contracting (especially risk-share or outcomes based) initiatives

Get Started Now Without Taking on Undue Risk.

There is no need to wait until the market figures all of this out. By starting small with motivated hand-picked partners and working incrementally, the manufacturer and partner can begin to understand the data, the drivers, and the metrics. It all starts with a dialogue.

- 1) A candid discussion with potential partners about your interest in specific kinds of engagements.
- 2) A portfolio of project concepts or arrangements surrounding identified needs, localized “Centers of Excellence” or clinical leaders’ interests
- 3) A White Board Session. Team members meet, analyze & weigh options to determine priorities
- 4) Identify & assign clinical and business staff with leadership and organizational skillsets to create “go – no go” list
- 5) Adopt best practices for contracting productively and collaboratively
- 6) Generate (for each contract or project engagement) a clear set of goals to stay compliant with federal, state laws & regulations
- 7) Use Project Management Disciplines. Manage each agreement as a “Project”. Gather real-world evidence or the artifacts required of the agreement including baseline and ongoing results to review and validate the contract hypothesis.

3. Allow the parties to start with a project that can frame out the factors and metrics about the use of a product, supporting future projects or price discount arrangements with lower risk.
4. Can facilitate the gathering of required data components for these shared-risk arrangements
5. Do not interfere with traditional contracted customers (GPOs, health plans, Government pricing)

MYSME Manager Market Roll Out. Currently, the SME Health Systems leadership team is working with key hospital, IDN, & ACO executives and savvy pharmaceutical and device managers to bring the framework into every-day use by launching targeted projects in specific geographic areas.

Project Status	Company / Affiliate	Project ID	Project Name	Project Category	Form URL	Start Date	End Date	Instances to Date	Partner Project Lead	Partner Signatory	Sponsor Project Lead	Sponsor Signatory
Active	ACO America	59	33TB-TEST1 attendee hrs	Administrative	33TB Meeting Attendee Hrs	4/1/2016	4/1/2017	3	PamP Tate_ACO	PatrickS Taylor_ACO	PortiaP Fonda_NewB	SteveS Olaf_NewB
Active	ACO America	80	430 Parent	Patient Registry	49 Child Info Not Saving Use 51	4/1/2016	5/31/2016	2	PamP Tate_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB
Active	ACO America	71	44 April 25 Basic Tests	Patient Survey	44 Child Unique Pt 425	1/1/2016	12/31/2016	3	PamP Tate_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB
Active	ACO America	84	44 Invoice Phase 1	Patient Survey	44 Child Unique Pt 425	1/1/2016	3/31/2016	0	PamP Tate_ACO	PamP Tate_ACO	PortiaP Fonda_NewB	SteveS Olaf_NewB
Active	ACO America	85	44 Invoice Phase 2	Patient Survey	44 Child Unique Pt 425	4/1/2016	6/30/2016	3	PatrickS Taylor_ACO	PamP Tate_ACO	SaraP Oliver_NewB	SteveS Olaf_NewB
Active	ACO America	87	44 Invoice Phase 3	Patient Survey	44 Child Unique Pt 425	6/1/2016	9/30/2016	2	PatrickS Taylor_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB
Active	ACO America	86	44 Partner to Reject	Patient Survey	44 Child Unique Pt 425	4/1/2016	6/30/2016	5	PatrickS Taylor_ACO	PamP Tate_ACO	PortiaP Fonda_NewB	SteveS Olaf_NewB
Active	ACO America	73	45 Form Test	Presentation	45 MeetingProjDet-MeetingHours	4/1/2016	4/29/2016	2	PamP Tate_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB
Active	ACO America	77	47 4/28 Test	Presentation	47 See Issue 138 Table Entries	4/1/2016	12/31/2020	7	PamP Tate_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB
Active	ACO America	78	48 Edit Example Issue 136	Patient Outcomes	48 MeetingProjectDetails-Attendee Hours	1/1/2016	4/29/2016	4	PamP Tate_ACO	PamP Tate_ACO	SteveS Olaf_NewB	SteveS Olaf_NewB

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- Tim Richards is a Senior Partner of SME Health Systems and Principal at Cambria Health Advisory Professionals. Tim has over 30 years of experience in sales, managed markets, and managerial experience in mid-size pharmaceutical companies. Tim has broad-based experience in managed markets strategy development, pricing and contracting strategies, managed markets new product launch plans, external corporate policy and communication and third party data profiles and functions. Tim has led and managed Commercial teams focusing on all payer channels, as well as institutional and long-term care channels. Tim has a BS in Marketing from Marquette University and an MBA from DePaul University with a concentration in Finance and Marketing. **Contact Information:** Phone: 203-247-3023 Email: trichards@healthadvisoryprofessionals.com