Mini Summit XVII: The New Marketplace: Value-Based Contracting and Other New Developments

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Agenda

- Value Based Contracting (VBC) the current environment
- The Impact on Government Pricing Calculations
- The Regulatory Climate and VBC
- Q&A

VBC Environment

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.

VBC Is Clearly Gaining Momentum Via A Range Of Drivers

Several industry trends and events suggest that VBC is gaining critical momentum and is even approaching a tipping point

Societal

Pharmaceutical prices have been the focus of intense public scrutiny in the past 18 months, and the public wants manufacturers to prove the value of their innovations and justify the corresponding prices

Provider

Since 2012, three prominent provider organizations put forth recommendations & tools to address the high cost of oncology drugs: the Mayo Clinic, the American Society of Clinical Oncology, and Memorial Sloan Kettering Cancer Center.

Payer

In market conditions where access is an increasingly important basis of competition, innovative payer contracting approaches are critical points of differentiation.

Policy

Policymakers continue to advocate for value-based pricing mechanisms (ACA enablement: CMMI, BPCI, MSSP, VBPM; CMS proposed Part B payment model; CMS Commissioner comments;

Priority Areas For VBC Have Been Identified By Stakeholders

Characteristics of products / indications appropriate for outcomes contacting

- Clearly identified population
- Clearly defined metrics / outcomes
- Monotherapy patient management
- Straightforward measurement
- Provider ability / willingness to manage patient protocols
- Products having uncertain efficacy and / or treatment duration
- High budget impact (high priced drugs in smaller indications)
- Modest differentiation / limited unmet need

Examples

Diseases of Interest

- Diabetes
- Hyperlipidemia
- Oncology
- MS
- RA
- HAE
- Sickle cell

Drug Classes of Interest

- Anti-diabetics
- PCSK9 inhibitors
- Anti-TNF
- Immune modulators (e.g. interferons, mAbs)
- Hormonal agents
- Anticoagulants

Pharma Efforts Can Be Traced Back A Decade

	Company (year)	Health Plan	Agreement	Results
	Janssen (2007)	UK NHS	Covered in UK in return for scheme where J&J reimburses NHS entire cost of tx for pts w/ inadequate response	Ops challenges experienced, but contract endured
	P&G / Sanofi (2009)	Health Alliance	Plan is reimbursed for any non-spinal fracture suffered by an Actonel patient (capped)	Fracture events consistent with trial data; Payments to plan 79% of cap
	Genomic Health (2009)	UHC	Plan reimburses list price for 18 mos; discount applied if patient is still on chemo despite support test result	N/A
	EMD Serono (2012)	Prime Therapeutics (BCBS PBM)	Favorable reimbursement terms for hitting targets in reducing ER visits and hospitalizations	N/A

Historical Barriers Are Waning Due To Improved Stakeholder Capabilities And Increasing Incentives

Structural Barriers

- Payer fragmentation (separate negotiation requirements)
- Limited provider integration (relative to EU)
- Health plan membership churn (particularly outside of large, regionally dominant systems)
- Increasing use of polypharmacy in many disease states
- Effectiveness of internal customer disease mgmt in some diseases

Operational Barriers

- Patient identification, metric definition agreement
- Siloed pharmacy and medical benefits
- Lack of customer / data source readiness
- Lack up alignment on contractual incentives (e.g. customer desire for upfront vs. downstream economic rationale)
- Need to reconcile with existing rebate-oriented contracts
- Solution implementation complexity; resource requirements
- Anti-kickback statutes

…And Presents Some Of Its Greatest Challenges

- **The bar has been raised**… New and higher hurdles exist to demonstrate economic value of new products; RWE has been cited as a major factor in recent decisions by retailers/PBMs related to:
  - Reimbursement status and level
  - Product utilization decisions
- **…and not just by commercial payers:** CMS has set an objective of 50% Medicare payments in value-based purchasing categories by the end of 2018. And while CMS does not explicitly consider cost in coverage decisions, cost has been cited as a reason for Medicare to open a national coverage analysis (e.g. Provenge's NCA two months post-approval – with a price tag of $93k)
  - **Companies are shifting focus accordingly…** Boards and the C-Suite are challenging employees to justify pricing, and to go to market in a value-based manner.
- **…and compliance risks abound**: safe harbors exist for communication of data (FDAMA 114), but guidance lags (19 years and counting…) and more safe harbors may be warranted (Lilly-Anthem)
  - Anti-Kickback concerns
  - Government Pricing concerns

Risk Shifting By Commercial Plans And CMS Has Increased Urgency & Incentives Among Providers

Bundled Payment / Shared Savings (*Selected Examples*)

- **Physicians**: Physicians can receive bonus payments based on lower drug costs or shift to lower cost medical management.
- **Cardiac and joint replacements**: one bundled payment upon admission to the hospital and extending 90 days post-op
- **Dialysis**: one bundled payment for all services related to dialysis, including drugs, diagnostic tests and self-dialysis training
- **IVIG**: per-visit payment for intravenous immune globulin administration that covers all associated costs

A Range Of Value-Based Arrangements Can Be Seen Today

Performance-Based Pricing

- Upside Model: up-front price with manufacturer sharing in any subsequent savings realized
- Downside Model: up-front price with manufacturer sharing in any subsequent losses realized
- Cohort Performance: price tied to patient population performance compared to control group
- Money-Back Guarantee: up-front price with refund where product not/less than effective
- Try-Before-You-Buy: free product up-front with price charged only where product effective

Course of Therapy Pricing

- Flat Pricing: single price per course of therapy regardless of amount of product needed
- Pricing Cap: per unit price up to certain volume with remainder free where additional product needed
- Interest is increasing, but difficult to implement

Indication-Based Pricing

- Same product has different pricing depending on indication for which it is used
- Increasing in use / exploration as more drugs are investigated across multiple indications

Annuity Pricing

- Product price/cost shared across payers that cover patient across his/her lifetime
- Nascent methodology

An Uptick In Activity Is Evident, Primarily Performance Based

	Company (year)	Health Plan	Agreement
trulicity	Lilly (2016)	Harvard Pilgrim	Improved formulary position in return for higher rebates if fewer Trulicity patients reach A1c target compared with those using other GLP-1 drugs
Entresto™	Novartis (2016)	Aetna (& Cigna & Harvard Pilgrim)	Preferred position in return for higher discounts if not hitting target reductions in hospitalizations
Effient (prasugrel) tablets	Lilly (2015)	Humana	Ties level of reimbursement to rate of hospitalizations
IRESSA™ gefitinib	AZ (2015)	Express Scripts	AstraZeneca will reimburse costs of the lung-cancer drug Iressa if a patient stops treatment before the third prescription fill

Government Pricing Considerations: Value Based Discounts

What are Value-Based Discounts?

- Arrangements where price to the customer depends on a patient health outcome or other patient experience
  - Rebate amount depends on whether a outcome measure is met (e.g. avoid hospitalization, avoid bone fractures, rate at which patients meet testing guidelines)
  - Manufacturer pays for treatment of complications
- Free trial – first cycle of therapy or first dose is free
- Duration of therapy caps – payor does not pay for more than x doses per patient
- Indication-specific pricing – price differs depending on, e.g., tumor type being treated

Recent Perspectives And/Or Guidance from CMS

- On November 20, 2015, the US Department of Health and Human Services convened a Pharmaceutical Forum: “Innovation, Access, Affordability, and Better Health” to address value-based pricing.
- On March 8, 2016, the Centers for Medicare & Medicaid Services (CMS) released the proposed **“Part B Drug Payment Model rule** which plans to test a new Medicare Part B payment model for reimbursement of ASP products.
  - The objective of the proposed rule is to test whether an alternative payment structure and/or use of value-based purchasing tools can reduce Medicare spend and improve quality of care to Medicare beneficiaries.
- On July 14, 2016, **CMS issued Manufacturer Release #99 (State Release # 176) which provided minimal guidance on value based purchasing (VBP) arrangements.**
  - The release indicated that manufacturers should refer and adhere to existing regulations when determining which transactions are eligible for Best Price, which is not new guidance.
  - The guidance did, however, encourage manufacturers to consider VBP arrangements with state Medicaid agencies.
  - Encouraged any manufacturer that has these arrangements to submit any issues or questions to the CMCS Division of Pharmacy at RxDRUGPolicy@cms.hhs.gov.

GP Background

- Drug manufacturers must report to the government data on commercial drug sales, as a condition of government reimbursement
- Medicaid Unit Rebate Amount = 23.1% of AMP or AMP – Best Price, plus additional rebate for inflation
  - AMP is average of sales to retail community pharmacies
- Reported metrics are calculated on a per unit basis -- per mg, ml, etc. – and at the NDC-9 level

GP Background (Cont'd)

- Medicaid Best Price is the lowest price paid in a quarter by any commercial customer, unless an exception applies
- A low Best Price means:
  - Higher rebates paid by the manufacturer on Medicaid utilization
  - Lower ASP for physician-administered drugs
  - Lower prices paid by 340B covered entities

Best Price Exclusions

- IHS, VA, DoD, PHS
- 340B Covered Entities (including DSH inpatient purchases)
- FSS purchases
- Designated SPAPs
- State veterans homes
- Any federal agency under a depot or single award contract
- Prices negotiated for manufacturer-sponsored drug discount cards
- Certain manufacturer coupons
- Non-contingent, free goods
- Bona fide service fees

- PBM price concessions, with exceptions
- Sales at "Nominal Prices" (< 10% of AMP) to specified customers
- Prices realized by manufacturers as a result of
  - Rebates paid to Part D Plans
  - Qualified retiree prescription drug plan rebates for Part D drugs
  - Medicaid rebates paid to state Medicaid plans (Must be approved by CMS if supplemental)

Best Price Effects / Per Unit Pricing

- Value-based discount could result in a very low per unit Best Price
  - Capped price
  - Per course of therapy price
  - Pricing that varies by indication, but indications have same NDC-9
- GP Options
  - Best Price exempt classes of trade
  - Outcome metric affects quarterly rebate percentage overall, instead of making a particular patient's product free or discounted
  - Best Price protection in contract terms

Bundled Sales

- Medicaid definition: "[A]n arrangement regardless of physical packaging under which the rebate . . . is conditioned upon the purchase of the same drug, drugs of different types . . . or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary) . . . "
- Definition may be interpreted as creating "bundles over time": satisfying a contingency in one quarter affects discounts in another quarter
- Is a free trial a bundled sale?
  - E.G., 100% rebate on patient's first course of therapy, 0% rebate for any subsequent courses of therapy?

Bundled Sales (cont'd)

- GP Options:
  - Evaluate whether any outcome being measured is in fact a performance requirement
  - Keep the period over which outcomes are being measured short
  - Make the discount percentage uniform over the period being measured
  - Be prepared to allocate discounts if discount percentage will vary

Data Issues

- Who collects the data necessary to measure the relevant outcome?
- Does the manufacturer pay the customer?
- Is this a bona fide service fee?
  - Fair market value;
  - Bona fide, itemized service performed on behalf of the manufacturer;
  - Manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and
  - Not passed on in whole or in part to a client or customer of an entity.

Legal and Regulatory Frameworks

FDA Promotional Rules vs. Value Based Contracting

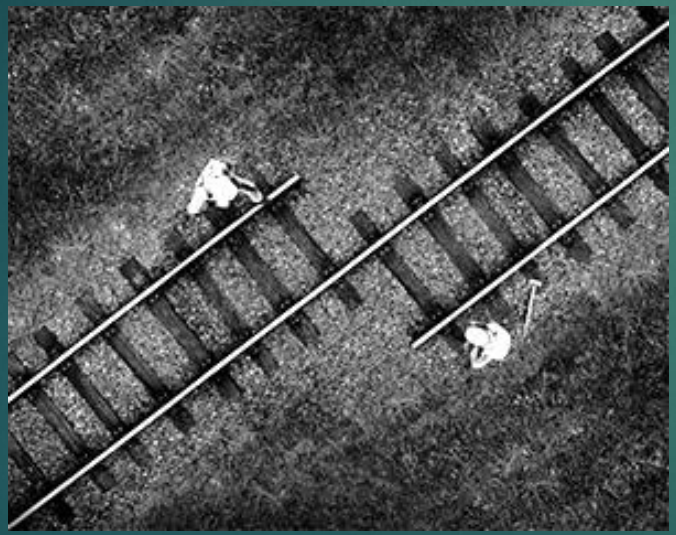
- **An arrangement that measures performance based on actual use, which may include off-label uses**—whether as a baseline for payments or as a metric to assess future payments—carries a risk that it could be viewed as creating inappropriate incentives for that use

- *Example*: A drug is approved for combination use with a steroid, but steroids are no longer commonly used in the disease state. Does the manufacturer encourage use without a steroid when it enters a risk sharing agreement in which none of the plan's patients receives the steroid?

- *Example*: A manufacturer sells a drug that was approved based on a surrogate endpoint, such as LDL-C lowering. Can its contracts with payers measure quality outcomes based on a treatment outcome that payers find more clinically meaningful, e.g., lower cardiovascular morbidity and mortality?

What Legal and Regulatory Frameworks Apply?

The goals of value-based arrangements (e.g., payment based on actual results) and current legal/regulatory frameworks are fundamentally misaligned



Applicable guidelines laws/regs include the "usual suspects:"

- FDA promotional rules
- Government price reporting requirements
- Anti-kickback statute
- Medicare Part B and Part D requirements
- Patient privacy/HIPAA

Uncertainty for Manufacturers

CMS also completely fails to acknowledge or address various regulatory requirements with which manufacturers must comply that stand in tension with the Model – many of which CMS and other agencies are actively working to enforce. CMS's failure to recognize – let alone, attempt to resolve, the following regulatory conflicts is additional evidence that this Model has not been well-conceived and should be fully withdrawn.

Public Comments on the Part B Demo

In order to facilitate the use of value-based contracting in the private sector, CMS and other agencies in the Department of Health and Human Services (HHS) must address the significant regulatory hurdles that currently impede use of this tool. These include legal impediments such as best price reporting requirements, privacy constraints on payer/provider information-sharing with manufacturers, FDA restrictions on the promotion of off-label drug usage, and Anti-Kickback Statute (AKS) requirements.

Another critical area that CMS does not discuss in the Proposed Rule relates to FDA's limitations on promotion of off-label indications by manufacturers—which is another key regulatory consideration, and one that CMS should work with FDA to address.

Operational and Compliance Considerations

Key Operational and Compliance Considerations

Category	Operational Considerations	Legal/Compliance Considerations
Metrics	• Does the **package insert** reflect value-based measures that are relevant to payers? • Is the payer **willing** to work with the manufacturer to create measurable, realistic measures of value? • How can a manufacturer ensure that only **on-label metrics are considered** in calculating rebate amounts – especially when a payer's definition of a term may differ from that in the label (e.g. "hospitalization")? • Who will reap the long term benefits of the chosen metric(s)?	• Are the proposed metrics consistent with the PI? • Are a manufacturer's discussions about proposed value-based measures compliant with applicable laws? • Is the manufacturer appropriately conveying data and claims in the course of contract negotiations? • Could a manufacturer's entry into a proposed value-based contract be interpreted as evidence of intent? • How can manufacturers maintain an appropriate separation between medical and commercial uses of information that may be obtained through value-based contracts? h

Key Operational and Compliance Considerations (CONT'D)

Category	Operational Considerations	Legal/Compliance Considerations

Data/Systems	• Does the payer have **access** to the data needed to create the relevant metrics?
	• Does the payer have the **resources** to track the relevant metrics?
	• Once collected, how will the data be **validated** so that it can be trusted by the manufacturer?
	• Will the data be stored in a **reliable, auditable system** ?
	• Once validated, in what form and under what conditions/terms will the data be provided to the manufacturer?
		• Are the systems and data flows set up to comply with HIPAA and other health data privacy and security laws and regulations? E.g.,
		  • restrictions on the use of data by the manufacturer
		  • data review for auditing purposes
		• Will the data be collected in a way that enables the manufacturer to fulfill pharmacovigilance obligations that may arise from the generated data?

Key Operational and Compliance Considerations (CONT'D)

Category	Operational Considerations	Legal/Compliance Considerations
Contracting & Reporting	• How will **adherence thresholds** be set and measured (to protect both parties against underuse/undercompliance)? • How will we **translate the HEOR language into contract language**? • How do we address the fact that these contracts may **extend past the standard contracting lifecycle?**	• Are anti-kickback prohibitions implicated by any of the contractual terms? Could the terms be interpreted as establishing incentives to skew clinical decision-making?

What Can We Do?

Lifting the Barriers to Adoption of VBC Arrangements

VBC arrangements can be made more feasible by creating a policy environment conducive to allowing health plans and manufacturers to enter into VBC arrangements. This may include:

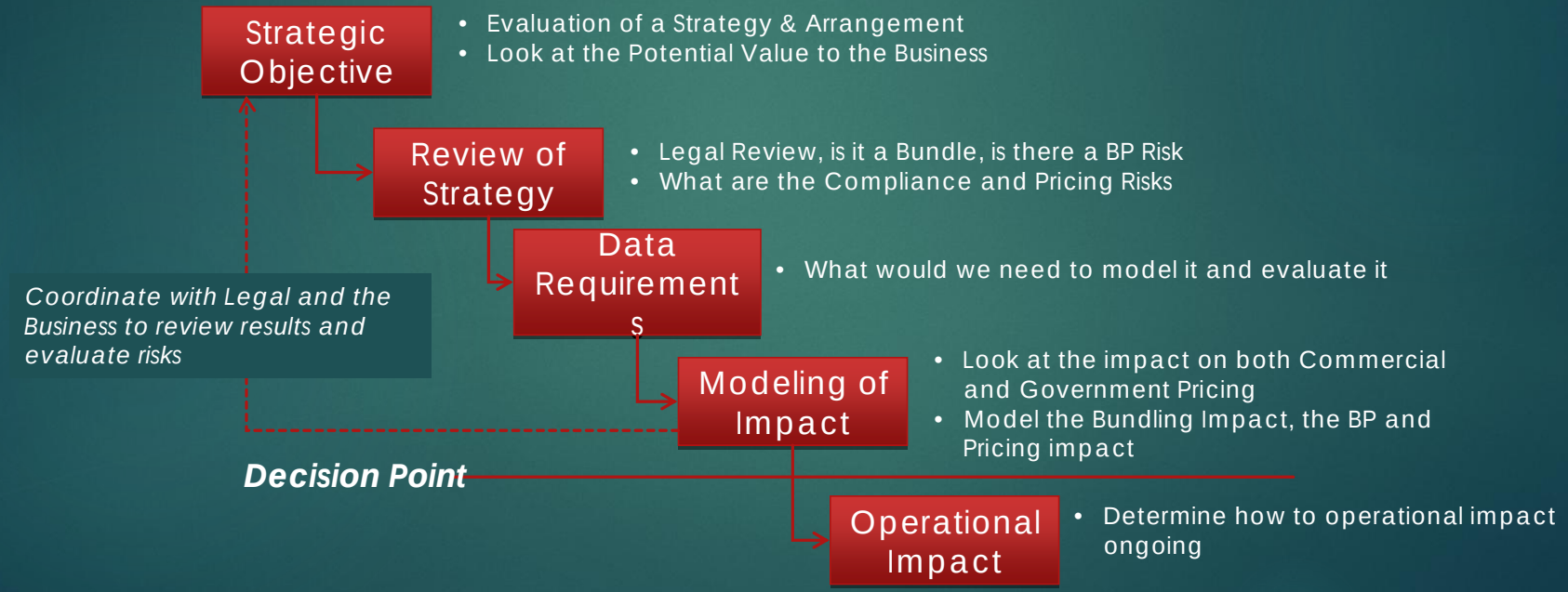
Creation of legislative/regulatory exceptions for Best Price and all other relevant government pricing calculations and requirements as they relate to products sold or transferred under value-based contracts

Additional safe harbors to the federal Anti-Kickback Statute (AKS) that protect value-based contracts from AKS liability.

The OIG could update guidance in order to explicitly protect VBC arrangements when certain criteria are met.

Evaluating Potential Arrangements: Bridging Commercial Strategy To Operations

- Discussion is now much along the strategic objectives and value, and the operational considerations, it is also important to look at the layers bridging strategy and operational impact



Questions