



While the rest of the healthcare system is paying for value, payments for drugs largely continue to be stuck in a 20th century construct that focuses on price, regardless of the health outcomes of each patient. Anthem and Eli Lilly and Company are collaborating to help accelerate the transition towards a value-based system with policy proposals that will help drive payment innovation. Read more at [ThinkAnthem](#) and [LillyPad](#).

Promoting Value-Based Contracting Arrangements

Eli Lilly and Company and Anthem | January 29, 2016

The following memorandum outlines Eli Lilly and Company and Anthem's joint perspective on creating legislative and regulatory options designed to promote value-based contracting arrangements for manufacturers and commercial health plans.

POLICY GOAL: Create a policy environment conducive to allowing health plans and manufacturers to enter into a variety of value-based contracting arrangements, aligned with the shift toward value-based payment and the goal of promoting access to high-value care. 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, as well as additional safe harbors to the federal Antikickback Statute (AKS) that protect value-based contracts from AKS liability.

Background and Context

Policymakers and industry are looking for opportunities to drive quality, create savings, and slow cost growth in the healthcare system. In particular, stakeholders are increasingly focused on value and increasing the use of treatments, products, and services that are both clinically effective and efficient. In fact, by 2018 the Department of Health & Human Services intends to link 80 percent of Medicare payments to value, and 50 percent to alternative payment models like bundled payments.¹

While there has been substantial innovation in how health plans and the government reimburse for hospital and physician payments (with physician payments moving further in this direction following the recent Medicare and Children's Health Insurance Program (CHIP) Reauthorization Act), payment for prescription drugs is often based on more traditional outcomes (e.g., volume of product purchased). Given the role that prescription drugs play in the treatment of and spending for many complex and chronic conditions, health plans and manufacturers seek greater opportunity to align payment with quality, accountability, and coordination. Ultimately, these arrangements can encourage access to high-value medicines and treatments and ensure that patients are getting the best value for their healthcare dollars. However, existing legal and regulatory barriers are stifling this innovation.

Traditional drug pricing contracts typically establish a fixed price for the product that remains in place throughout the benefit year. This may include flat pricing (e.g., price per unit) or volume arrangements. For example, a health plan and manufacturer may agree that if spending for a particular medicine exceeds a certain level, the manufacturer will offer the health plan a discount or rebate on the unit price. In contrast, value-based arrangements may condition payment or drug price based on patient-level clinical or economic outcomes (e.g., a 1 percent reduction in HbA1c levels for certain patients with diabetes). As illustrated in Appendix A, these arrangements represent a fundamental departure from traditional contracting and may require investment from both manufacturers and health plans. In order to design a contract that makes payment for a therapy contingent on patient outcomes, for example, the manufacturer and the health plan must agree on how to reliably, accurately, and appropriately measure outcomes and categorize patients as "responders" or "non-responders." In addition, both plans and manufacturers need to designate staff to monitor and execute the agreement, a further investment by both parties.

¹HHS.gov. "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value." 26 January 2015. Available at: <http://www.hhs.gov/news/press/2015pres/01/20150126a.html>

Value-based arrangements allow both parties to share in the risk associated with individual patient outcomes and spending for a particular medicine. These contracts offer important benefits for consumers, health plans, and manufacturers. Consumers, in particular, may enjoy earlier or less managed access to new medicines when payments are aligned with value. Over time, identifying and encouraging use of the highest-value products could both improve patient outcomes and curb healthcare spending growth. Although manufacturers and health plans seek opportunities to invest in these innovative models, existing legislation and regulations raise concerns, including:

- **Anti-Kickback Statutes:** Federal and state fraud and abuse laws are designed to protect patients, health plans, and the healthcare system overall from fraud, waste, and abuse. The Anti-Kickback Statute (AKS) prohibits offering or receiving remuneration (broadly defined) to induce or reward referrals for items or services paid for by federal healthcare programs. Statutory and regulatory safe harbors protect certain arrangements from AKS liability, but it is unclear how enforcement agencies would apply these safe harbors to value-based arrangements.² AKS violations carry significant financial and other penalties.
- **Government pricing:** Manufacturers are required to report pricing data to the federal government to determine Medicaid rebates; Medicare Part B payment rates; the 340B program ceiling price; and the maximum price that certain government agencies can be charged. Because these reporting requirements did not foresee and were not designed to be compatible with value-based contracting, they could make it exceptionally difficult for a manufacturer to enter into a value-based contract. For example, current Medicaid rebate regulations would require that rebates paid to a commercial health plan in the context of a single value-based contract be made available to Medicaid programs, even though Medicaid programs would not be subject to the key design features of the value-based arrangement (for high level examples of value-based arrangements, please see Appendix A).

In order to capitalize on the potential of value-based arrangements for consumers, industry, and other healthcare stakeholders, policymakers should adapt standards related to kickbacks and government pricing to accommodate these novel contracts. Absent such clarification, legislation and regulations that reflect traditional contracting will continue to impede innovation.

Promoting Value-Based Arrangements

The goals of value-based contracting approaches align with the shift toward high-value care. Such agreements seek to make more efficient use of healthcare resources, potentially reducing costs throughout the system, encouraging use of the most efficient and effective care, and improving patient outcomes.

Clearer safe harbors and guidance for all stakeholders could promote the adoption of value-based models. For example, stakeholders could benefit from:

- Expansion or creation of new statutory or regulatory safe harbors, including by the OIG, to the AKS that more clearly protect innovative, value-based contracting arrangements (under a defined set of requirements);
- Amendments to the statutory and regulatory definitions of certain prices reported to the government (e.g. Best Price) to define the terms for excluding payments made pursuant to value-based contracts;
- Regulations clarifying how manufacturers can incorporate value-based contracts in their price reporting calculations; and,
- Pilots or demonstration programs with commercial health plans that adapt the government pricing rules to test how value-based contracts impact reported government price figures, and in turn, Medicaid rebate amounts and 340B ceiling prices.

Existing Legislative and Operational Barriers

FRAUD AND ABUSE

As described above, current fraud and abuse guidance may have a chilling effect on value-based arrangements. For example, if a manufacturer and health plan entered into an arrangement under which the manufacturer accepted risk for treatment failure (e.g., the health plan would only pay for a drug for patients with positive treatment outcomes), this could be viewed as remuneration offered to encourage the health plan to favorably cover the manufacturer's product. Additionally, the OIG has not issued sub-regulatory guidance addressing value-based contracting arrangements, leaving stakeholders with little to no insight on OIG's position on the risk of fraud and abuse they pose.

To alleviate stakeholder concerns related to fraud and abuse, regulations and guidance could be updated to establish regulatory³ safe harbors, and the OIG could update guidance⁴ in order to explicitly protect these arrangements when certain criteria are met. Congress could also consider establishing a statutory safe harbor. The safe harbor eligibility criteria can be designed to minimize risk of fraud and abuse in these arrangements. For example, the OIG could require that value-based payments be determined in advance, and could not vary during the term of a contract.

³42 C.F.R. § 1001.952

⁴66 Fed. Reg. 23731 (May 5, 2003)

GOVERNMENT PRICING

Manufacturers' government price reporting obligations may also have a chilling effect on the development of value-based contracts. Largely, this is a result of the way pricing, discounts, and contracting arrangements affect government price reporting, and in turn, manufacturer obligations under a variety of federal programs.

Best Price and Average Manufacturer Price

Implications for Best Price are the most immediate, important factor to consider with respect to manufacturer incentives created by value-based contracting. Best Price is the pricing benchmark Medicaid uses to ensure state Medicaid programs never pay more than the lowest price offered for a particular therapy. Best price is set based on the single "lowest price available from the manufacturer during the rebate period to any entity⁵ in the United States."⁶ Best Price is affected by manufacturer rebates, discounts, or other price concessions to commercial health plans, and setting a new Best Price can lead to significantly increased Medicaid rebate and 340B program liability for manufacturers. Under the current regulations, payments from manufacturers to health plans under a value-based contract would almost certainly need to be included in Best Price calculations. For example, if a manufacturer offered a health plan a rebate equal to 60 percent of the list price of a product for each enrollee who did not respond to treatment, and negotiated a payment rebate equal to 20 percent of the list price for patients who did respond, the 60 percent rebate would determine the product's Best Price for all patients. If the list price were \$1,000, this would result in a Best Price of \$400 (assuming that there were no greater discounts/rebates in the market; if so, Best Price would be even lower). As the example below shows, reductions in Best Price can result in significant Medicaid rebate and 340B liability.

	List Price	AMP ⁷	Best Price (BP)	Medicaid Rebate Amount per Unit (AMP-BP) ⁸	340B Ceiling Price (AMP – Medicaid Rebate Amount)
Without value-based rebate (example)	\$1,000	\$950	\$700	\$250	\$700
With value-based rebate (including patients who do not respond to therapy)	\$1,000	\$950	\$400	\$550	\$400

* Assumes no additional "inflation-based" rebate

These reductions may create negative returns on value-based contracts for manufacturers. The Best Price statute and regulations could be updated to exclude from Best Price certain rebates and other price concessions paid from manufacturers to health plans that are the result of value-based contracting (e.g., additional rebates paid if a patient does not respond to treatment). CMS could also be authorized to create pilot programs to test how value-based contracts and alternative approaches to Best Price impact reported government price figures, and in turn, Medicaid rebate amounts and 340B ceiling prices.

Further complicating compliance with the price reporting rules is the fact that many value-based arrangements could constitute "bundled arrangements," which require complicated re-allocation of price concessions, either across products or across periods, and trigger additional disclosure obligations.

Average Sales Price

Best Price is not the only price point that would be impacted by value-based contracts. For medical benefit drugs (in general, those that are physician-administered), manufacturers are required to report Average Sales Price (ASP) to the Centers for Medicare & Medicaid Services (CMS) on a quarterly basis; ASP is used to set Medicare Part B reimbursement rates.⁹ ASP is defined as "the manufacturer's sales to all purchasers...in the United States for a drug or biological in the calendar quarter [excluding exempted sales] divided by...the total number of such units of such drug or biological sold by the manufacturer in such quarter."¹⁰ Like Best Price, rebates to commercial health plans are included in ASP, but unlike Best Price, ASP is an average price and is not determined by a single sale.¹¹

Manufacturers of medical benefit products may be concerned that substantial rebates offered to commercial health plans under value-based contracts would reduce ASP, and in turn, Medicare Part B reimbursement rates for their products. Relatedly, CMS may substitute Average Manufacturer Price, or AMP, for ASP under certain conditions. AMP is also used in determining Medicaid rebates, and a product's

⁵With certain exceptions, including most government purchasers and Part D plans.

⁶42 C.F.R. § 447.405

⁷Assumes AMP = 95% of List Price.

⁸As BP is used in this particular example, it is assumed that this price (AMP-BP) is greater than statutory requirements in this particular scenario.

⁹42 U.S.C § 1395w-3a(b)(1).

¹⁰42 U.S.C § 1395w-3a(c)(1).

¹¹42 U.S.C § 1395w-3a(c)(2). The ASP statute references the statutory definition of Best Price in defining what rebates and discounts are excluded from ASP; in other words, the same rebates and discounts that are excluded from Best Price are also excluded from ASP. Therefore, changes to the definition of Best Price would also impact manufacturer's ASP calculations.

340B ceiling price. Accordingly, it will be critical for policymakers to address the implications of value-based arrangements for government prices in a consistent and comprehensive manner.¹²

OPERATIONAL COMPLEXITY

Value-based arrangements are complex, and manufacturers and health plans will need to align expectations with respect to desired outcomes, data collection, appropriate safeguards for patient privacy, and other factors. Manufacturers and payers are willing to work through these challenges, but the up-front investments necessary to make value-based arrangements succeed underscore the importance of appropriate regulatory and financial protection.

Manufacturer reporting and operational responsibilities under current pricing rules also pose a challenge. Accurately calculating and reporting government pricing figures are extremely complex tasks. Many pharmaceutical manufacturers expend significant resources on these activities. Value-based arrangements, in which the ultimate “price” of a product may not be known for a substantial period of time after the product is sold, would introduce significant operational complexity into these calculations and potential for legal ramifications. Additionally, many innovative contracting arrangements do not price products on a per-unit basis; for example, a course of therapy or treatment regimen price may be used instead. Incorporating non-unit based pricing into government pricing calculations may be very complex.

Key Considerations for Implementation

Several strategic considerations are critical to ensure the success of value-based contracts under a new regulatory paradigm. First, value-based contracts must be properly defined through federal regulation in order to accommodate existing and future goals. The definition will need to establish whether a value-based arrangement must have certain core features (e.g., risk sharing) in order to be eligible for any legislative and regulatory carve-outs, and, if so, what those core features are. While defining such an arrangement is necessary to ensure stakeholders have a common understanding of the arrangement, the definition will need to be sufficiently flexible to allow for potential innovative structures that have yet to be developed.

The government should simultaneously assess how best to update relevant laws and regulations in order to accommodate these innovations. For example, regulators could develop a template memorandum of understanding for payers and manufacturers to use, or a sample agreement between a manufacturer and the government that would appropriately exclude value-based pricing concessions from reporting. In addition to updating directly relevant laws and regulations (e.g., those related to pricing), regulators will need to consider whether existing fraud, abuse, and monitoring paradigms protect all stakeholders – including patients – impacted by value-based arrangements.

Finally, it will be important to allow for the emergence of value-based arrangements as part of the broader health system transformation and assure continued efficiency for government programs and patient access. By creating an environment in which value-based contracts are permitted, increased collaboration between health plans and manufacturers to enter into value-based contracts presents a significant opportunity to drive quality and access, create savings, and slow cost growth, aligned with the value-based shift in the overall US healthcare system.

¹²It is important to note that AMP for 5i products, which are infused, instilled, implanted, injected, or inhaled products that are generally not dispensed through a retail community pharmacy, includes additional rebates. Further, if a particular product is not sent through a distributor for 90% of gross sales, then the Non-Federal Average Manufacturer Price (NFAMP) is affected as payer discounts are factored in due to the 90-10 rule.

Appendix A

The below graphic depicts the level of risk on behalf of the health plan and manufacturer as well as the degree of difficulty of implementation of value-based contracting arrangements.

	Traditional Discounting	Conditional Payment	Value-Based Arrangements
General Description	Drug price is established prior to coverage and fixed for the benefit year	Payment contingent on certain short-term health outcome or evidence collection target	Reimbursement is tied to clinical or process outcome at the individual patient level
Key Inputs	Negotiated discount or rebate	Pre-determined goal for a defined patient population (e.g., short-term treatment goal such as persistence)	Pre-determined goal for a defined patient population (e.g., 1% reduction in HbA1c, performance versus competitor, delay in disease progression)
Key Outcomes	Varies (e.g., flat pricing, volume of drug purchased)	Attainment of treatment goals or collection of additional evidence through research	Patient-level clinical or process outcome (may occur after benefit year ends)
Example	<ul style="list-style-type: none"> Market share-based rebating or price-volume arrangements Utilization cap or manufacturer-funded treatment initiation 	Coverage/payment with evidence development or conditional treatment continuation	Manufacturer provides rebate on products purchased for patients who fail to achieve desired outcome seriously consider aggressive utilization management criteria and stakeholders scramble for mid-year solutions.

Degree of Difficulty and Risk *The specifics of any type of value-based arrangement vary, and are negotiated by the plan and the manufacturer*

Source: J Carlson, et al. "Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare health plans and manufacturers." Health Policy. 2010 Aug;96(3):179-90.

Appendix B

The following tables outline the statutes and regulations by topic area as relevant for this memorandum.

Fraud & Abuse	
Legislative or Regulatory Change Desired	Corresponding Statute/Regulation
Addition of statutory safe-harbor to existing language	42 U.S.C. § 1320a-7b
Addition of regulatory safe harbors to existing language	42 C.F.R. § 1001.952
OIG guidance to pharmaceutical manufacturers should be updated	66 Fed. Reg. 23731 (May 5, 2003)

Government Pricing	
Definition Referenced	Corresponding Statute/Regulation
Statutory definition of Best Price	42 U.S.C. § 1396r-8
Regulatory definition of Best Price	42 C.F.R. § 447.505
Statutory definition of ASP ¹³	42 U.S.C § 1395w-3a
Regulatory definition of ASP ¹⁴	42 C.F.R. § 414.804

¹³Note that if the statutory definition of BP is updated to exclude value-based payments, they will also be excluded from the statutory definition of ASP due to the fact that the ASP statute cross-references the BP statute

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