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February 26, 2018

BY ELECTRONIC FILING (http://www.regulations.gov)

Daniel R. Levinson
Inspector General
Attn: Patrice Drew
Office of Inspector General, Regulatory Affairs
Department of Health and Human Services
Room 5541C Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Re: OIG-127-N Solicitation of New Safe Harbors and Special Fraud Alerts

Dear Inspector General Levinson:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to propose new or modified safe harbors to the Federal Anti-Kickback Statute (AKS).[1] PhRMA respectfully requests that the Office of the Inspector General (OIG) develop a new safe harbor to protect and encourage value-based arrangements. In this letter, we provide new data and analyses to support this recommendation.

PhRMA is a voluntary, non-profit association that represents the country's leading biopharmaceutical research companies. PhRMA's members are committed to compliance with the AKS and support the OIG's goal of "protect[ing] beneficial arrangements that enhance the efficient and effective delivery of health care and promote the best interests of patients, while also protecting the Federal health care programs and beneficiaries from undue risk."[2] As our healthcare system moves to one that rewards the quality and value of care, there is increasing demand that payment for medicines be more closely tied to a product's performance in individual patients or payers' patient populations. An OIG safe harbor that removes AKS uncertainty could encourage such value-based arrangements and, moreover, could yield important benefits for Federal health care programs and their beneficiaries. By aligning payments for medicines more directly with their value, these agreements can help to improve patients' health outcomes and maximize the benefits of healthcare spending.

As recognized in a recent report by the Duke Margolis Center for Health Policy, "[m]any stakeholders view [value-based agreements] as potentially driving more efficient healthcare delivery, with

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1 Social Security Act § 1128B(b), 42 U.S.C. § 1320a-7b.

2 79 Fed. Reg. 59,717, 59,719 (Oct. 3, 2014).

reductions in overall costs while improving patient outcomes."[3] Within the past year, real-world data has emerged to support this view. An Avalere survey of payers that engaged in outcomes-based contracts with manufacturers found that 38% of payers experienced improvement in patient outcomes and 33% experienced cost savings.[4] A PhRMA issue brief, released today, also presents new data on potential benefits including reduced cost sharing for patients.[5] Improving outcomes and reducing costs are critical goals shared by participants throughout the healthcare system—innovators, payors, providers, patients, and the Federal government.

Despite the potential benefits of these arrangements, the Federal Anti-Kickback Statute is chilling more widespread adoption.[6] The AKS is a broadly worded statute that can inadvertently discourage beneficial low-risk healthcare arrangements through the threat of civil, criminal, and/or administrative sanctions.[7] To reduce the risk that the broadly worded AKS would deter beneficial arrangements, Congress empowered the OIG to develop regulatory safe harbors.[8] It is important that the AKS safe harbors evolve to support new arrangements that, if properly structured, could help to improve health outcomes, promote competition, and contain overall healthcare spending without raising risk of fraud and abuse. To date, the OIG's annual solicitations have elicited numerous proposals, from multiple stakeholders, to develop a safe harbor for value-based arrangements. In addition, over the past year, the Healthcare Leadership Council released a paper recommending modernization of the AKS in the area of value-based care,[9] and the Academy of Managed Care Pharmacy, the Network in Excellence in Health

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3 Duke Margolis Center for Health Policy, *Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products* (Dec. 2017), at 7,10, https://healthpolicy.duke.edu/publications/overcoming-legal-and-regulatory-hurdles-value-based-payment-medical-products.

4 Avalere Health, Payer Perspectives on Outcomes Contracting (May 22, 2017).

5 PhRMA, *Delivering Results for Patients: The Value of Value Based Contracts* (Feb. 2018), https://www.phrma.org/report/value-of-value-based-contracts.

6 PhRMA, *Barriers to Value-Based Contracts for Innovative Medicines: PhRMA Member Survey Results* (Mar. 2017), https://www.statnews.com/wp-content/uploads/2017/03/PhRMA_ValueBased_MemberService_R2122-2.pdf; Alison Ward et al., *Regulatory, Legal Uncertainties Are Barriers to Value-Based Agreements*, Health Affairs Blog (Nov. 4, 2016), https://www.healthaffairs.org/do/10.1377/hblog20161104.057443/full/.

7 Today, the risk of discouraging beneficial arrangements is even greater than in the past. As you know, the Affordable Care Act added language to the AKS stating that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the civil False Claims Act]." 42 U.S.C. § 1320a-7b(g).

8 42 U.S.C. § 1320a-7b(b) (requiring OIG to develop safe harbors); 42 U.S.C. § 1320a-7d (requiring an annual solicitation seeking proposals from the public for new or modified safe harbors and Special Fraud Alerts). Even before the 1996 law requiring the annual solicitation for safe harbor proposals, OIG acknowledged the Congressional expectation that it should "formally re-evaluate the anti-kickback regulations on a periodic basis, and . . . solicit public comment at the outset of the review process." Medicare and State Healthcare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952 (July 29, 1991) (quoting H.R. Rep. No. 85, part 2, 100th Cong. 1st Sess. 27 (1987)).

9 Healthcare Leadership Council, *Health System Transformation: Revisiting the Federal Anti-Kickback Statute and Physician Self-Referral (Stark) Law to Foster Integrated Care Delivery and Payment Models* (Feb. 2017), https://www.hlc.org/app/uploads/2017/02/HLC_StarkAntiKickback-White-Paper.pdf.

Innovation, and the Duke-Margolis Center have all released papers recommending creation of a new AKS safe harbor for value-based arrangements.[10]

We appreciate your willingness to engage in discussions regarding a safe harbor for value-based arrangements and your continued consideration of this important issue. In the remainder of this letter, we describe: (1) new data and analyses regarding value-based arrangements and why they matter; (2) why a new safe harbor to protect value-based arrangements is needed; and (3) how a safe harbor could encourage value-based arrangements while appropriately protecting Federal health care programs from fraud, waste, and abuse.

I. NEW DATA ON VALUE-BASED ARRANGEMENTS

A. Taxonomy of Value-Based Arrangements

As described above, pharmaceutical companies are increasingly being challenged by payors and providers to demonstrate the benefits of innovative medicines in new ways. Despite regulatory uncertainty and data-collection obstacles, some companies have been pursuing new arrangements in the commercial marketplace that (unlike traditional volume-based payment arrangements) tie payment for a medicine more closely to its performance in the real world. These arrangements can take many forms. Today, PhRMA is releasing a new issue brief, *Delivering Results for Patients: The Value of Value Based Contracts*, providing a taxonomy for describing some of the categories of value-based contracts for pharmaceuticals.[11] This taxonomy is reflected in Figures 1 and 2, below.

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[10] Academy of Managed Care Pharmacy, *AMCP Partnership Forum: Advancing Value-Based Contracting*, 23 JMCP 1096 (Nov. 17, 2017), available at https://www.jmcp.org/doi/abs/10.18553/jmcp.2017.17342; Network for Excellence in Health Innovation, *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals* (Mar. 2017), https://www.nehi.net/publications/76-rewarding-results-moving-forward-on-value-based-contracting-for-biopharmaceuticals/view; Duke Margolis Center for Health Policy, *Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products*, supra note 3.

[11] PhRMA, *Delivering Results for Patients: The Value of Value Based Contracts*, supra note 5. The PhRMA taxonomy is not an exhaustive list of all possible types of value-based arrangements.

Figure 1: Taxonomy of Value-Based Contracts

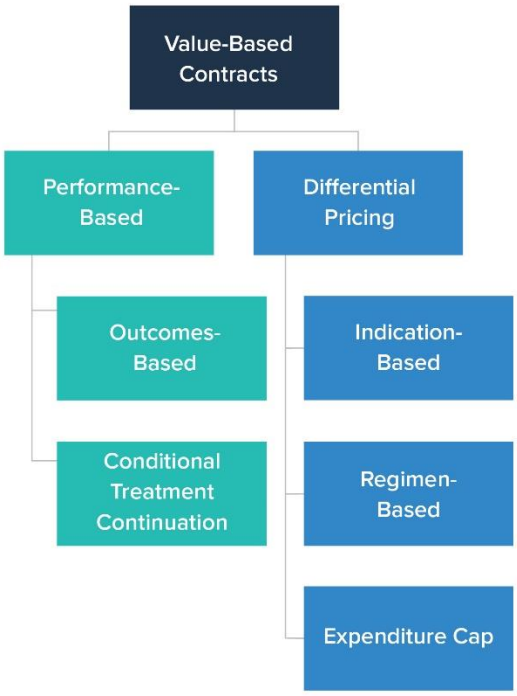

Figure 2. Glossary of Value-Based Contract Types

Contract Label	Description
Outcomes-Based Contract	A contract designed to tie costs or discounts to patient outcomes. This is currently the most common type of publicly disclosed value-based contract.
Conditional Treatment Continuation	An arrangement in which continuation of coverage of treatment is conditioned on meeting short-term treatment goals, frequently complemented by free trial of the medicine.
Indication-Based Pricing	A contract in which the net price of a medicine varies for different indications based on an agreement between the contracting entities.
Regimen-Based Pricing	A contract in which the net price of a medicine decreases when a patient must take a second medicine to make the treatment regimen more effective.
Expenditure Cap	An agreement which limits medicine cost per patient to a certain negotiated threshold. This has been implemented as a version of indication-based pricing for infused cancer medicines.

This taxonomy is consistent with previously published classifications of payer and manufacturer arrangements.[12] It is also consistent with the materials PhRMA previously provided to OIG and provides information about certain additional categories of agreements, such as conditional treatment continuation and regimen-based pricing. A copy of the issue brief is appended to this letter.

The taxonomy refers to an overarching category of "performance-based" arrangements, which includes the subcategory of "outcomes-based contracts" as well as a similar subcategory termed "conditional treatment continuation." Manufacturers may enter into outcomes-based contracts with payors where the net cost of a drug hinges on its clinical or cost performance in patients covered by the payor.[13] Performance may be measured through clinical endpoints such as Hemoglobin A1c for diabetes, through reduction in medical costs, or through measuring adherence as a proxy for the drug's effectiveness, among other approaches. As an example, under an outcomes-based arrangement, the payor may pay one price for a medicine if the medicine achieves agreed-upon outcomes and may pay less (or nothing at all) if the drug does not produce the agreed-upon outcome. This type of arrangement generally requires collection and timely submission of data on relevant outcomes experienced by patients taking the drug as well as data on patient adherence to the prescribed treatment regimen. So that patients receive the full benefit of the drug, the manufacturer is generally not penalized for poor outcomes resulting from non-adherence. In one arrangement, for example, a manufacturer promised to refund patients and payors up to six months of their prescription costs if a cholesterol-lowering product did not help them lower LDL cholesterol to a certain degree determined by their healthcare provider.[14] In another case, a manufacturer agreed to pay rebates on its rheumatoid arthritis drug if patients taking the drug scored below certain levels on six criteria, including patient adherence, dose escalation, and steroid interventions.[15] Under a third arrangement, a manufacturer of a heart failure medication agreed to reduce the drug's cost to payors if the heart failure hospitalization rate of patients using the drug exceed a specified threshold.[16]

Outcomes-based agreements may also involve manufacturers replacing their product for free or paying for additional therapies required when the product does not meet the agreed-upon outcomes. For example, a manufacturer of an anemia treatment agreed to replace the product for free if it was used appropriately but the patient did not respond to treatment.[17] In another reported example, the manufacturer

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[12] See Nazareth T, Ko JJ, Sasane R, Frois C, Carpenter S, Demean S, Vegesna A, Wu E, Navarro RP. *Outcomes-Based Contracting Experience: Research Findings from US and European Stakeholders*, 23(10) JMCP 1018-26 (Oct. 2017); and Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL, *Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance Based Reimbursement Schemes Between Healthcare Payers and Manufacturers*, 96(3) Health Policy 179-90 (Aug. 2010).

[13] Today, outcomes-based agreements are the most common type of publicly disclosed value-based agreement. Other taxonomies sometimes use the terms "risk sharing agreements" or "performance based risk sharing agreements" synonymously with outcomes-based agreements.

[14] Network for Excellence in Health Innovation, *Rewarding Results: Moving Forward on Value-Based Contracting for Biopharmaceuticals*, supra note 10 at 9.

[15] Ibid.

[16] Ibid.

[17] Duke Margolis Center for Health Policy, *Developing a Path to Value-Based Payment*, supra note 3.

of an osteoporosis drug agreed to help pay the cost of treating fractures in patients who suffered them despite taking the drug and adequately following the prescribed treatment regimen.[18]

Also falling into the category of "performance-based" contracts are conditional treatment continuation agreements. These are arrangements in which continuation of coverage of a treatment is conditioned on meeting short-term treatment goals, in some cases complemented by a free trial of the medicine. For example, manufacturers could enter into agreements for therapies where an expected outcome can be measured after a short period of time (*e.g.*, 30 or 60 days), and payors are not billed for the drug unless the patient meets the predetermined outcome during the agreed-upon period.

The second broad category of value-based contracts is known as "differential pricing," and includes at least three sub-categories of arrangements: indication-based pricing, expenditure cap contracts, and regimen-based pricing. Indication-based pricing is a contract in which the net price of a medicine varies for different indications. For a drug with multiple FDA-approved indications, manufacturers traditionally do not vary the net price to payors depending on the indication for which a unit is prescribed. But for many multiple-indication drugs, the expected health gain or the total cost of treatment may vary depending on the indication for which they are used.[19] Under indication-based pricing, products used for different indications have different net prices.

For example, a manufacturer recently expressed interest in using a rare disease drug for cardiovascular conditions, but the rare disease price would not be competitive with other cardiovascular medicines.[20] These arrangements may permit manufacturers to charge differential prices for various indications (*e.g.*, lower prices where needed for greater competition), creating incentives for manufacturers to study, and payors to cover, a greater range of indications. As a result, indication-based agreements have the potential to lower costs, increase patient access, and increase competition in relevant therapeutic classes.

Another type of differential pricing is the expenditure cap agreement, which limits medicine costs to a certain negotiated threshold. For example, this type of contract has been implemented as a version of indication-based pricing for certain infused cancer medications.

"Regimen-based" pricing is another example of a value-based arrangement with the potential to increase patient access and lower payor costs. Under these contracts, the net price of a medicine decreases when a patient is prescribed a second medicine to make the overall combined treatment regimen more effective. There are many drugs that are FDA-approved for use either as monotherapy or in combination with other drugs, and combination regimens are becoming more common as clinical trials are

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[18] Andrew Pollack, *Drug Deals Tie Prices to How Well Patients Do*, NY Times (Apr. 22, 2009), http://www.nytimes.com/2009/04/23/business/23cigna.html.

[19] See, e.g., Peter Bach, *Indication-Specific Pricing for Cancer Drugs*, 312 JAMA 1629 (Oct. 2014), https://jamanetwork.com/journals/jama/fullarticle/1915075.

[20] See, e.g., Denise Roland, *The Price Dilemma over a $16,000 Drug*, Wall St. J. (July 12, 2017), https://www.wsj.com/articles/the-price-dilemma-over-a-16-000-drug-1499832421.

showing that certain products are more effective or safer when used together than when used alone.[21] For example, the National Cancer Institute has explained that "combination therapies are viewed as a central way to overcome one of the most vexing issues in cancer therapy: treatment resistance."[22]

Although combination regimens improve outcomes in many cases, the cost to patients and payors can be high, because they are paying for two or more drugs instead of one. Regimen-based pricing agreements could be used to lower the net-of-rebate price of a medicine when patients are prescribed a combination regimen to treat their condition more effectively, thereby reducing the cost of therapy regimens and expanding patient access to these important regimens. Multiple manufacturers have recognized the need to lower prices for combination therapies.[23] The net-of-rebate payment for a drug would thus vary depending on whether it is prescribed as monotherapy or needs to be taken in combination with an additional drug (or drugs). The idea is that while each drug is valuable, payers may demand a lower price when it is used in combination with another drug.

B. Why Value-Based Arrangements Matter

Within the past year, increasing study of value-based arrangements for pharmaceuticals and the adoption of certain value-based arrangements within the commercial marketplace[24] have generated new data on the conceptual and real-world benefits of value-based arrangements. As outlined in the framework presented in the new PhRMA issue brief, value-based arrangements have the potential to: (1) allow payers to provide more support for appropriate use of medicines; (2) expand patient access to new treatment options, thus broadening the choices available to patients and their physicians and increasing competition; leading to (3) better patient adherence and more appropriate medicine use; and ultimately to (4) improved patient outcomes, allowing payors to realize value for their overall healthcare spending.[25]

It is critical to understand the role that outcomes-based contracts can play in facilitating patient access to new therapies, including breakthrough medicines for rare and devastating diseases, and in improving patient outcomes. Innovative medicines have the potential to transform patients' lives by treating

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[21] See, e.g., World Health Organization, *Introduction and Rational Use of New Drugs/Regimens for TB Treatment* (Nov. 2015), http://www.who.int/tb/publications/newdrugs_factsheet.pdf; National Cancer Institute, *Identifying Nova Drugs Rehabilitation to Overcome Treatment Resistance* (Dec. 21, 2016).

[22] National Cancer Institute, *NCI Almanac: A New Tool for Research on Cancer Drug Combinations* (May 12, 2017), https://www.cancer.gov.news-events/cancer...blog.../nci-almanac-drug-combinations.

[23] Ben Hirschler, *New Cocktails to Test Limits of Cancer Drug Pricing*, Reuters (August 3, 2015), https://www.reuters.com/article/us-health-cancer-prices-analysis/new-cocktails-to-test-limits-of-cancer-drug-pricing-idUSKCN0Q80AK20150803.

[24] Avalere's recent survey of 45 payors representing 183 million covered lives found that more than half of payors surveyed either have an outcomes-based contract in place or are currently in negotiations. Avalere Health, *Payer Perspectives on Outcomes-Based Contracting* (May 22, 2017). A separate survey by PWC found that one quarter of pharmaceutical company executives say their company has participated in a value-based arrangement. Of those who have participated, nearly one-third (32 percent) have engaged in more than 20 of these arrangements. PWC, *Launching Into Value: Pharma's Quest to Align Drug Prices with Outcomes* (Sept. 2017), https://www.pwc.com/us/en/health-industries/health-research-institute/publications/value-based-drug-pricing.html.

[25] PhRMA, *Delivering Results for Patients: The Value of Value Based Contracts*, supra note 5.

segments of the population in desperate need of medical advances. For instance, currently, more than 1,500 potential gene therapy treatments are in research and development by dozens of pharmaceutical companies, including nearly 600 targeting cancers and 500 for rare and debilitating or deadly conditions.[26] A payor that might otherwise decline to cover a new drug (or that would cover the drug only with significant utilization management restrictions or high cost sharing) due to uncertainty about the percentage of the payor's member population that would benefit from the drug, might increase access to the drug if the manufacturer shared the risks of the drug's performance. For example, the issue brief released by PhRMA today suggests that value-based agreements may result in a roughly 28% cost sharing reduction for the drugs in question.[27] By reducing payors' risk, these agreements may make newer drugs more accessible to patients who will benefit from them and could increase competition in relevant drug classes.[28]

Payers have repeatedly recognized the importance of the risk sharing that can occur with outcomes-based arrangements. As Steve Miller, the Chief Medical Officer of Express Scripts, has emphasized, "[v]alue-based contracting can help to ensure that payors and patients are not on the hook when a treatment isn't effective."[29] A new article on outcomes-based contracts in the U.S. noted that:

> Recent interest in OBAs [outcomes-based agreements] has emerged largely from payers' desire to reduce the risks associated with high-cost pharmaceuticals with uncertain real-world outcomes and effectiveness. By using OBAs, payers can shift some risk to manufacturers with the potential incentive of improving market access for the manufacturer's product, thus improving patient access to novel therapies and potentially generating important real-world evidence.[30]

In addition, multiple payers joined the Academy of Managed Care Pharmacy partnership forum that recommended a new safe harbor to the Anti-Kickback Statute.[31]

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[26] Steven Miller, *Gene Therapy Holds Great Promise, But Big Price* (Sept. 21, 2017), http://lab.express-scripts.com/lab/insights/drug-options/gene-therapy-holds-great-promise-but-big-price.

[27] PhRMA, *Delivering Results for Patients: The Value of Value Based Contracts*, supra note 5.

[28] See, e.g., Lee Staley, *A Drug's Worth: Why Federal Law Makes it Hard to Pay for Pharmaceutical Performance*, 98 B. U. L. Rev. 303, at 310 (2018) ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers. . . .A manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors.").

[29] Steven Miller, *Gene Therapy Holds Great Promise, But Big Price* (Sept. 21, 2017), supra note 26.

[30] JD Brown et al., *Payer and Pharmaceutical Manufacturer Considerations for Outcomes-Based Agreements in the United States*, 21 Value In Health 33, 35 (Jan. 2018) (emphasis added), https://www.sciencedirect.com/science/article/pii/S1098301517303315. See also Garrison LP et.al., *Private Sector Risk Agreements in the United States: Trends, Barriers, and Prospects*, Am J Manag Care. 2015: 21(9):632-640 ("Based on our interviews, US payers leverage -- or would like to leverage -- RSAs [risk-sharing agreements] as a way to reduce uncertainties about a product's clinical value, performance, or budget impact, as they allow payers and patients to get experience with the medication.").

[31] Academy of Managed Care Pharmacy, *AMCP Partnership Forum: Advancing Value-Based Contracting*, supra note 10.

CMS has also recognized the critical role of value-based arrangements for new therapies in a recent press release in which CMS Administrator Seema Verma reinforced the agency's belief that "current healthcare payment systems need to be modernized in order to ensure access to new high-cost therapies, including therapies that have the potential to cure the sickest patients."[32] CMS announced that it is committed to exploring innovative pricing systems that reflect the value delivered to patients, and that "[a]s part of larger efforts to support the President's priority [to lower drug costs], CMS is working actively with all stakeholders . . . on innovative payment arrangements. These arrangements may, for example, include outcome-based pricing for medicines in relation to clinical outcomes."[33]

Differential pricing agreements also may expand patient access to medications and reduce the costs of medicines. For example, regimen-based pricing would lower the costs of combination therapies, easing the way for payors to broaden access to combination regimens when they are the most effective treatment for individual patients and ultimately improving patient outcomes. Moreover, by allowing manufacturers to charge different prices for a drug depending on the indication for which it is used, indication-based pricing agreements could facilitate earlier availability of new treatments, new indications, and broader patient access.

In the longer term, if the number and scope of value-based agreements increase, more information will be generated on the effects of different products and treatment regimens on different patient populations and subpopulations.[34] Real-world evidence on how different treatments affect patients with a certain disease (or subgroups of patients with a certain disease) may be available to providers and patients making individualized, patient-centered treatment decisions, and to payors developing formulary decisions and coverage policies. Over time, this should shift drug utilization toward drugs with greater clinical value and greater ability to reduce hospitalization and other costly services, resulting in better health outcomes and lower overall healthcare spending. Policies that reduce obstacles to value-based arrangements may thus improve patient care and also curb spending—presenting a rare opportunity that we hope the OIG will seize.

II. WHY A VALUE-BASED ARRANGEMENT SAFE HARBOR IS NECESSARY

We believe that most value-based arrangements pose minimal risk of fraud and abuse under the Anti-Kickback Statute, and it is black letter law that failure to meet a safe harbor does not mean that an arrangement violates the statute. However, without a safe harbor specifically addressing value-based arrangements, many entities are hesitant to enter into such agreements, given the significant penalties associated with the AKS.

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[32] CMS, *Innovative Treatments Call for Innovative Payment Models and Arrangements*, https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2017-Press-releases-items/2017-08-30-2.html (emphasis added).

[33] Ibid.

[34] For example, one study conducted in Sweden concluded that "stakeholders benefited from analysis of real-world (postmarket) data (in addition to pre-launch, trial-based data)" collected under a value-based pricing agreement. See Deloitte, *Value-based Pricing for Pharmaceuticals: Implications of the Shift from Volume to Value* (2012), http://deloitte.wsj.com/cfo/files/2012/09/ValueBasedPricingPharma.pdf.

Because OIG's current safe harbor regulations do not expressly address value-based purchasing models, there can be uncertainty about how to apply the existing safe harbors to these new arrangements. Many types of value-based arrangements—including, but not limited to, indication-based arrangements, for example—may fit within existing safe harbors. However, lack of clarity in the safe harbors, variable interpretation by courts, aggressive *qui tam* relators and enforcement officials, and the outdated nature of the safe harbors creates uncertainty that discourages some payors, providers, and manufacturers from embracing this important innovation in healthcare payment. Clear Anti-Kickback Statute guidance addressing value-based arrangements would help stakeholders structure value-based arrangements with confidence and may encourage broader adoption.

The discount safe harbor, last substantively revised in 1999, limits the adoption of value-based arrangements in several ways. First, by their very nature, most value-based agreements involve a performance component—for example, collecting and analyzing outcomes data, and measures to ensure that patients take the medication as prescribed (so that patients get the greatest value from their medicine, cost savings from the agreement are optimized, and manufacturers are not held responsible for poor outcomes caused by non-adherence). However, the safe harbor states that "[s]ervices provided in accordance with a personal or management services contract" are not discounts protected under the safe harbor,[35] and confusion exists about when discounts may be conditioned on the performance of specified activities by the buyer. For example, the Department of Justice (DOJ) has asserted in litigation that discounts "conditioned on [a buyer's] agreement to take specific actions to promote utilization" of the seller's products fell outside the AKS discount exception.[36] The DOJ has also stated that "[i]f a reduction in price is conditioned on more than a simple purchase, it is not a mere 'discount,' but rather a form of remuneration whose legitimacy must be evaluated under the anti-kickback statute separate and apart from the statutory discount exception or regulatory discount safe harbor."[37] The line DOJ draws between acceptable performance-based discounts and unlawful kickbacks is unclear, and manufacturers and payors do not know how the line would be drawn in a value-based agreement context.

Second, the discount safe harbor imposes ambiguous disclosure obligations on buyers, which have different disclosure obligations depending on their subcategory.[38] The provisions on seller and offeror obligations contain cross-references that make it difficult to understand what these obligations are (particularly with respect to discounts to "charge-based" and cost-reporting buyers).[39] In addition, the preambles to the 1991 and 1999 final rules suggest that sellers and offerors qualify for safe harbor protection provided they "fully and accurately report [the] discount on the invoice, coupon or statement submitted to the buyer" and "the actual purchase price [reflected on the invoice, coupon or statement]

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35 42 CFR § 1001.952(h)(5)(vi).

36 United States ex rel. Banigan v. Organon USA Inc., No. 07-12153 (D. Mass 2013) (Stat. of Interest on Behalf of the U.S., Dkt. No. 144).

37 United States ex rel. Herman v. Coloplast Corp., No. 1:11-cv-12131 (D. Mass 2016) (Stat. of Interest on Behalf of the U.S., Dkt. No. 170).

38 42 CFR § 1001.952(h)(1)-(3).

39 42 CFR § 1001.952(h)(2)(iii), (3)(ii)-(iii).

accurately reflects the discount,"[40] indicating that accurately reporting the amount of a discount to the buyer satisfies a seller's disclosure obligation. But at least one case has held that sellers must require buyers to disclose the terms of the discount agreement (*i.e.*, any activities the buyer must perform to earn the discount).[41] This surprising holding underscores the confusion surrounding the discount safe harbor.

Finally, the discount safe harbor may not protect arrangements with hospitals in which health outcomes are measured and net prices adjusted over timeframes beyond two years. The safe harbor requires that a cost-reporting buyer claim the benefit of a discount within a maximum of two years.[42] This requirement could limit adoption of value-based agreements with hospitals where rebates depend on longer-term outcomes (*e.g.*, arrangements involving gene therapies and other potential curative therapies where a longer time horizon is needed to account for the possibility that a disease may reemerge later in a patient's life or that safety risks will be identified over time).

The warranty safe harbor, as currently written, also does not adequately protect the full range of value-based agreements. For example, while the safe harbor could protect certain value-based arrangements, it does not protect manufacturers if they pay "any remuneration to any individual (other than a beneficiary) or entity for any medical, surgical, or hospital expense incurred by a beneficiary other than for the cost of the item itself."[43] Therefore, the safe harbor might permit manufacturers to offer a payment to cover replacement of their own product (as long as the payment does not exceed "the cost of the item itself"), but it is unclear whether or not it would protect value-based agreements in which the manufacturer would pay the medical expenses caused by a drug's failure to perform as expected (for example, follow-up treatment where the warranted product did not achieve the desired clinical outcome). Further, this safe harbor would not be relevant to differential pricing agreements.

III. VALUE-BASED ARRANGEMENT SAFE HARBOR PROPOSAL

PhRMA appreciates OIG's ongoing dialogue with stakeholders regarding a safe harbor that would protect beneficial value-based arrangements that present a low risk of fraud and abuse. Below, we discuss why value-based arrangements perform favorably under the criteria OIG considers when establishing safe harbors. We then outline several key features and safeguards we respectfully recommend OIG contemplate when developing any safe harbor covering value-based arrangements.[44]

A. Value-Based Arrangements Perform Well Under Statutory Criteria for Establishing Safe Harbors

As you know, the statutory provisions permitting annual solicitation of safe harbor proposals provide criteria that OIG may consider when modifying or establishing safe harbors. Specifically, the

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40 56 Fed. Reg. 35952 (July 29, 1991); 64 Fed. Reg. 63518 (Nov. 19, 1999).

41 United States ex rel. Lisitza v. Johnson & Johnson, 765 F. Supp.2d 112, 125 (D. Mass, 2011) ("While the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not.").

42 42 C.F.R. § 1001.952(h)(1)(ii)(B).

43 42 C.F.R. § 1001.952(g)(4).

44 42 U.S.C. § 1320a-7d(a)(2).

statutory language permits OIG to consider the extent to which providing a safe harbor for the specified payment practice may result in an increase or decrease in:

- access to healthcare services;
- the quality of healthcare services;
- patient freedom of choice among healthcare providers;
- competition among healthcare providers;
- the ability of healthcare facilities to provide services in medically underserved areas or to medically underserved populations;
- costs to Federal health care programs, and
- the potential overutilization of healthcare services.[45]

The law also instructs the OIG to consider whether a proposed safe harbor would affect the existence (or nonexistence) of any potential financial benefit to healthcare providers that varies based on their decisions about whether to order a healthcare item or service or to arrange a referral to a particular practitioner or provider and provides that OIG may also consider any other appropriate factors.[46]

We believe that arrangements falling within a properly structured value-based arrangement safe harbor are likely to improve patient health outcomes, improve patient access and choice of therapies, increase competition, curb Federal health care program spending, and present minimal risk of fraudulent or abusive practices (such as interference with clinical decision-making and overutilization). As explained below, the agreements that would fall within an appropriately structured safe harbor fare well under the factors that are commonly examined by the OIG and listed in 42 U.S.C. §1320a-7d(a)(2).

First, these arrangements should not interfere with clinical decision-making or encourage overutilization. OIG has often expressed concern about overutilization (unnecessary or excessive use of healthcare items or services, which can waste government funds and potentially harm beneficiaries) and interference with clinical decision-making. However, a value-based arrangement that fits within the safe harbor parameters proposed below poses a low risk of overutilization or interference in clinical decision-making. Value-based arrangements seek to reverse the flawed incentives of the traditional fee-for-service model, namely its potential to reward volume and thus prompt overutilization. The goal of value-based arrangements is instead to align payment for a product more directly with evidence of its clinical and cost outcomes. Therefore, these arrangements reward good clinical and cost outcomes (as specified in the agreement) rather than high utilization. Due to this incentive structure, the agreements eligible for protection would not encourage or reward high utilization of the product.

Payors in value-based arrangements will also serve as a check on overutilization through their role in negotiating the specific clinical and cost outcomes that determine price adjustments. A payor could, for example, negotiate for a downward price adjustment or an expenditure cap if the total cost of care (or the costs of a component of care like drug costs or costs of hospitalizations) for enrollees treated with a new product were high. Payors have no interest in increasing their spending and, unless they agree to the overall structure of a value-based arrangement, the parties will not reach agreement. Payors also are well-

[45] 42 U.S.C. § 1320a-7d(a)(2).

[46] Ibid.

positioned to work with the manufacturer on protocols to encourage and assess enrollees' adherence (so that the product's measured performance is not skewed by patients with poor adherence). Activities to promote adherence—which often are a key part of value-based agreements—should also boost the effectiveness of the medicine and reduce the total healthcare costs a payor incurs for an enrollee.

Moreover, rather than undercutting independent clinical decision-making by the patient and his or her healthcare providers, these arrangements may improve clinical decision-making, because they would reduce barriers to access that can prevent physicians from prescribing new and potentially more effective therapies. Thus, patients or their healthcare providers will likely have more treatment options available from which to choose (as the payor is likely to provide coverage for the drug without imposing unduly restrictive utilization management requirements or excessive cost sharing).

Differential pricing agreements also would promote clinically grounded decision-making and expand patient choice. Regimen-based pricing cuts combination therapy costs for payors and can thus result in broader access. This permits physicians to prescribe a combination therapy regimen or a single product, depending on which treatment strategy would work better for an individual patient. Likewise, indication-based pricing would increase competition in the pharmaceutical market by allowing manufacturers to cut prices to compete in conditions where the drug is not cost-competitive. Otherwise, a drug with multiple indications having different levels of effectiveness must have the same per-unit pricing for both indications, meaning that one or both indications have a price out of line with the market for that condition. Removing this uniform per-unit pricing constraint allows payors to cover the drug for each indication—without overpaying.[47]

Second, these arrangements are unlikely to give rise to quality of care or patient safety concerns. Instead, value-based arrangements should improve the quality of patient care. For example, indication-based agreements would give providers and patients additional safe and effective therapies from which to choose in deciding on a treatment strategy for a particular indication. Outcomes-based arrangements, by their nature, would create extra financial incentives for manufacturers to ensure that their products work safely and effectively for the patients using the medicines. Better identification of a product's effects in different subpopulations or other differing circumstances will result in the product being used more in cases where it improves the quality of care and less in cases where it is ineffective or less effective than competitors.

Third, these arrangements would expand, rather than interfere with, patients' access to medicines and the choice of medicines available to them. Many payors increasingly exclude or limit coverage of costly newer therapies. Outcomes-based contracts, by "help[ing] to ensure that payers and patients are not on the hook when a treatment isn't effective,"[48] permit payors to expand access to new therapies with the potential to save lives or deliver better outcomes. Indication-specific agreements would also promote patient access to medicines and increase their choice of therapies. As discussed above, these agreements

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[47] Another situation where indication-based pricing can yield these benefits is where a drug has similar effectiveness for two indications, but the dose needed to make the drug effective varies significantly between the two indications, resulting in the drug having similar effectiveness but much different treatment costs depending on the indication for which it is used.

[48] Steven Miller, *Gene Therapy Holds Great Promise, But Big Price*, supra note 26.

could make it financially feasible for payors to cover a medicine for multiple indications. If the payor and its enrollees must pay the same amount for indications in different classes, the payor may not view the drug as competitively priced in certain classes, and therefore not cover the drug, place it on a tier with high cost-sharing, or impose restrictive utilization management requirements, making the product unavailable to patients who could benefit from using it for that indication and might lack other options. Permitting a payor to negotiate an appropriate price for each indication may expand patients' choices and spur competition in the relevant therapeutic areas.

Finally, these arrangements would not inappropriately increase costs, and more likely would ultimately produce overall cost savings for Federal health care programs. Value-based agreements reflect manufacturers' intention to stand behind the value of their products. For example, as described in the *Delivering Results for Patients: The Value of Value-Based Contracts*, value-based agreements can reduce costs by lowering spending on medical services or through greater manufacturer rebates and discounts on the medicine. Looking only at diabetes, if value-based arrangements can reduce the costs of managing that disease by five percent, they could save over $12 billion annually.[49] In addition, value-based arrangements may reduce the cost of medicines as manufacturers pay higher rebates for medicines that do not meet performance objectives under outcomes-based contracts, or through larger discounts for combination therapies.

Moreover, an expansion of value-based arrangements in Medicare Advantage or Medicare Part D could benefit the government through reduced plan spending, reduced reinsurance costs, and reduced plan bids. Within Medicare Part D's competitive, market-based structure, innovator companies contract directly with Part D plans and Medicare Advantage (MA-PD) plans. To the extent that value-based arrangements improve use of medicines, they could reduce MA plan spending, which could reduce MA plan bids. Improved use of medicines in Medicare Part D could also reduce spending on medical services under Medicare Parts A and B. In addition, by increasing rebates paid by innovator companies, value-based arrangements could reduce reinsurance costs. If value-based arrangements reduce plans' risk and their expected costs, such arrangements would permit plans to offer Medicare lower plan bids.

Longer-term cost savings to Federal health care programs could also result from the data value-based agreements can generate about how well a product works, both generally and for particular patient groups. This data can yield savings by enabling better-informed coverage policies and formulary decisions by Federal health care programs (including by private plans that deliver Medicare or Medicaid benefits) and better-informed treatment decisions by providers and patients.

For example, data from value-based agreements may indicate which patient subpopulations respond well—or do not respond well—to a drug. This information would help providers to make prescribing decisions based on the drug's value to the relevant patient subpopulation, creating opportunities to reduce costs by reducing the prescribing of drugs that prove ineffective in certain subgroups. In addition, patients could save money if plans put products on a formulary tier with lower cost-sharing due to the plan having reduced risk, or due to knowing that patients previously treated with the drug achieved good outcomes. The PhRMA study published today, which found that from 2015-2017, cost-sharing was 28% below the market average for certain plans that had announced an outcomes-based

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[49] PhRMA, *Delivering Results for Patients: The Value of Value Based Contracts*, supra note 5.

agreement, suggests that these contracts may have accounted for lower patient cost sharing. Reduced cost sharing may, in turn, increase adherence, which could further improve patients' health and reduce their healthcare spending. This suggests that value-based arrangements could potentially start a "virtuous cycle" for cost-containment and improved health for many Americans.

B. Safe Harbor Structure and Safeguards

Based on the above, we respectfully recommend that OIG develop a safe harbor for the types of value-based arrangements described herein. We believe that any such safe harbor should include the following key features.

Any value-based agreement safe harbor should protect appropriately structured arrangements between manufacturers and purchasers (*i.e.*, direct or indirect purchasers or a party that arranges for the purchase of products, such as health plans, payors, PBMs, or providers) that provide for warranties or value-based price adjustments based on measurable clinical or cost outcomes. The types of outcomes to be included should capture the types of arrangements described herein, including direct clinical outcomes, measures that reliably predict clinical benefits, proxies for clinical outcomes like medication adherence, or measures that involve the cost of caring for patients treated by the product.[50]

The safe harbor should also protect contract performance activities that are related to the administration of the value-based arrangement. For example, this should include functions related to measuring outcomes under the agreement (*e.g.*, hiring a third party to collect data and calculate the metrics underlying a rebate agreement), resolving disputes regarding outcomes achieved, or facilitating patients' adherence to their providers' prescribed treatment regimen.

In terms of safeguards to deter fraud and abuse and to help identify arrangements qualifying for safe harbor protection, a safe harbor should require that value-based arrangements specifically identify any value-based price adjustment, warranty, or contract performance activity included in the agreement. It should also require that the written value-based agreement set out all material terms of the arrangement (*e.g.*, the method for computing the value-based price adjustment or warranty and the key roles and responsibilities of each party). OIG could also consider requiring the parties to provide a copy of the agreement upon request; however, we would emphasize that these agreements are highly sensitive business documents and should be treated as confidential and proprietary and not disclosed by the government. OIG could also require that purchasers fully comply with any applicable Federal health care program requirement to report the price, price adjustment, or warranty for the product.

A safe harbor could also include patient protections around contract performance activities, such as requiring the manufacturer to disclose its role, if any, in adherence support communications, as well as safeguards to protect the physician-patient relationship and maintain the independence of health care provider decision-making (including, for example, provider decisions to change to a different drug or treatment regimen, to discontinue a drug or treatment regimen, or to extend a drug or treatment regimen).

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[50] A clinical or cost outcome should include whether the product is used as monotherapy or used with additional therapies, as measured under the agreement itself or in a previous study.

Finally, the safe harbor could include safeguards addressing the use and distribution of patient data, for example, requiring that any data collected to administer a value-based agreement must be used in compliance with applicable privacy laws.

* * *

PhRMA appreciates this opportunity to provide additional information regarding the need for a value-based arrangements safe harbor. We urge the Office of Inspector General to act on this important issue. We would be pleased to speak with your further or to respond to any questions you may have.

Respectfully submitted,

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Executive Vice President and General Counsel

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Assistant General Counsel

Delivering Results for Patients: The Value of Value-Based Contracts

PhRMA

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FEBRUARY 2018

Executive Summary

Biopharmaceutical manufacturers and insurers are interested in exploring a range of innovative approaches to paying for medicines in the private market. Sometimes called value-based contracts, value-based arrangements or results-based contracts, these innovative contracting approaches can benefit patients and the U.S. health care system as the barriers that limit these arrangements are addressed and more contracts occur.

Outcomes-based contracts are one widely publicized type of value-based contract in the market today. An analysis of a subset of plans that announced at least one outcomes-based contract indicates their potential to reduce cost sharing. From 2015 to 2017, cost sharing was 28 percent lower for certain plans that announced an outcomes-based contract compared to the market average, suggesting these contracts may have led to lower patient cost sharing.

While value-based contracts are being pursued today, the barriers to these contracts mean that it is unreasonable to judge the potential benefits of these contracts by looking at those in the market today. By aligning manufacturer and payer incentives to improve patient outcomes, these arrangements present a range of potential benefits, including reducing medical costs, lowering spending on medicines and improving patient access, affordability and outcomes. For example, there is an enormous opportunity to improve use of medicines in diabetes. If new value-based contracts can improve use of medicines and reduce the burden of diabetes in the United States by as little as five percent, these contracts could save over $12 billion annually.

Introduction

In the past decade, the health care system in the United States has begun a transformation as stakeholders seek to tie more health care payments to value instead of the volume of services provided. One important goal of this shift is to direct health care utilization to where it is most effective, increasing value for spending in the U.S. health care system. Meanwhile, biopharmaceutical manufacturers are facing an increasingly competitive environment and are producing ever more innovative medicines that cure diseases or significantly improve patient outcomes.

In response to these dynamics, payers and manufacturers are exploring a range of new value-based contracts that tie reimbursement for medicines more closely to value for individual patients. These voluntary, private arrangements include performance-based contracts that link payment to demonstrated patient outcomes, varying payment based on how a medicine is used and other forms of risk sharing.

While existing performance-based contracts have likely benefited patients, biopharmaceutical research companies have identified a range of barriers that limit the scale and scope of value-based contracts in the market. These barriers, which were identified in both a survey of PhRMA's members and a survey of payers, include concerns about how the contract might affect price reporting metrics, issues with potentially implicating the federal anti-kickback statute and uncertainty about U.S. Food and Drug Administration rules regarding manufacturer communications.[1,2]

Because of these barriers, the potential impact of value-based contracts is not accurately represented by the contracts that have been publicly announced to date. The scale of individual contracts and the number of contracts could be dramatically increased by addressing these barriers. In addition, the types of contracts in the market could evolve with greater flexibility from policymakers. **Figure 1** presents a taxonomy for value-based contracts, which builds on previously published classifications of payer and manufacturer contracting and reimbursement arrangements.[3,4] **Figure 2** provides definitions for potential contract types that might occur, become more frequent or broaden in scope by addressing regulatory barriers. The types of contracts shown are just examples; other types of value-based contracts may exist in today's market or could be developed in the future.

Figure 1: Taxonomy of Value-Based Contracts

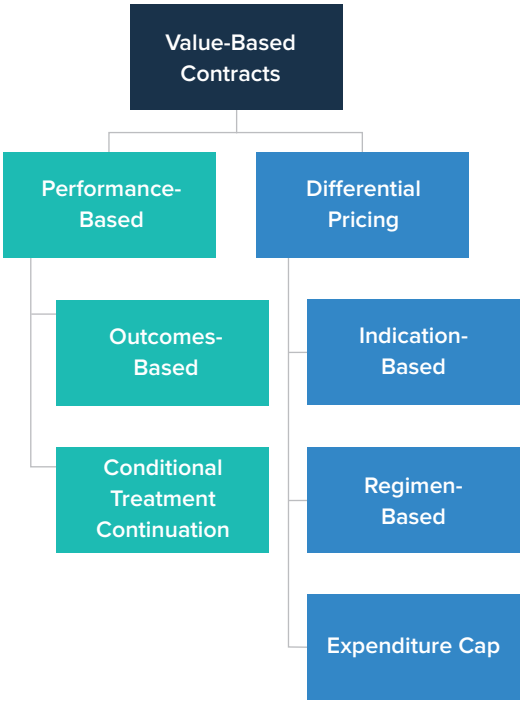


Figure 2. Glossary of Value-Based Contract Types

Contract Label	Description
Outcomes-Based Contract	A contract designed to tie costs or discounts to patient outcomes. This is currently the most common type of publicly disclosed value-based contract.
Conditional Treatment Continuation	An arrangement in which continuation of coverage of treatment is conditioned on meeting short-term treatment goals, frequently complemented by free trial of the medicine.
Indication-Based Pricing	A contract in which the net price of a medicine varies for different indications based on an agreement between the contracting entities.
Regimen-Based Pricing	A contract in which the net price of a medicine decreases when a patient must take a second medicine to make the treatment regimen more effective.
Expenditure Cap	An agreement which limits medicine cost per patient to a certain negotiated threshold. This has been implemented as a version of indication-based pricing for infused cancer medicines.

New value-based contracts have the potential to benefit patients and the health care system in several ways.

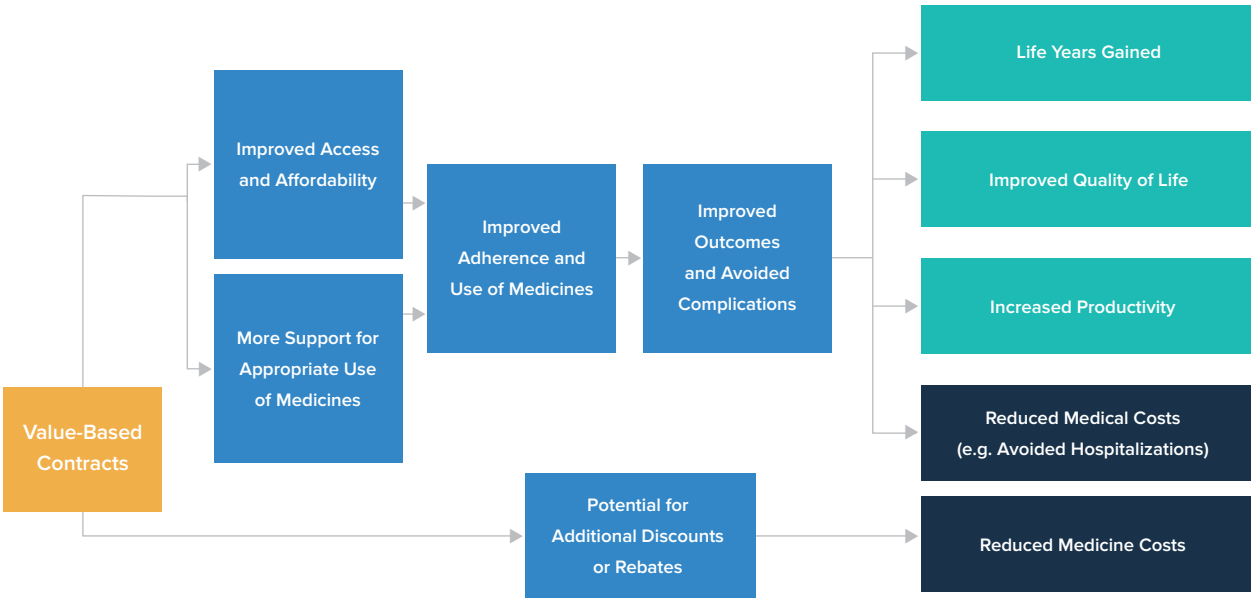
1. **Value-based contracts can potentially improve patient outcomes.** This could occur if payers are able to provide broader access to innovative medicines, as manufacturers reduce the payer's risk for suboptimal outcomes. It could also occur as these contracts allow payers or manufactures to do more to support appropriate patient use of medicines.

2. **Value-based contracts can potentially reduce medical costs.** Medicines can prevent spending on medical services by preventing hospitalizations, emergency visits or other costly results of poorly controlled disease.[5] As described above, supporting better use of medicines through value-based contracts could help drive these savings in medical costs. This may also reduce patient cost sharing.

3. **Value-based contracts can potentially reduce the cost of medicines.** It might also occur if manufacturers pay higher rebates for patients who do not meet agreed upon outcome targets under an outcomes-based contract. Patients may also save if rebates are passed onto them or the medicine receives better formulary position and thus lowers cost sharing. Value-based contracts can move prescription medicine payment away from unit-based approaches and better align stakeholder incentives around value.

There is some evidence of these benefits in today's value-based contracts. A 2017 Avalere survey found that 38 percent of payers with outcomes-based contracts experienced improvements in patient outcomes and 33 percent experienced cost savings.[6] A framework illustrating the range of potential benefits from value-based contracts is shown in **Figure 3**. There could also be other, broader benefits to patients and society not documented here.[7]

Figure 3. Conceptual Framework for Potential Benefits of Expanded Value-Based Contracts

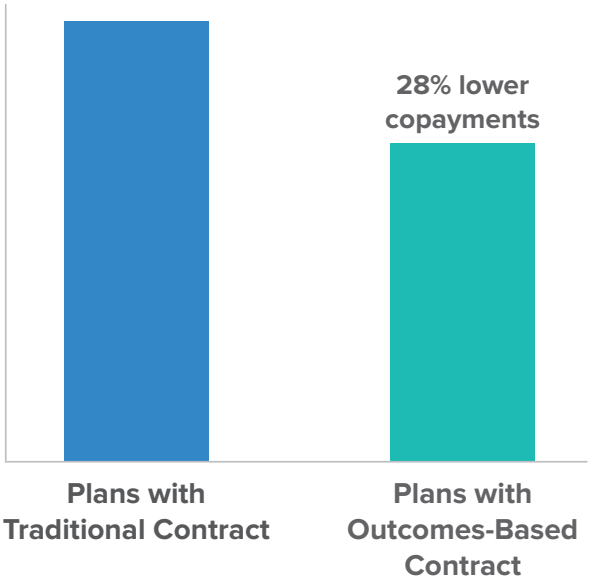


Patient Access Improvements from Current Outcomes-Based Contracts

Value-based contracts for biopharmaceuticals in the United States are still relatively new. One sub-type, outcomes-based contracts, has received much stakeholder attention. Seventy percent of commercial health plans indicated a favorable attitude towards outcomes-based contracts, with nearly a quarter of plans reporting that they have implemented at least one such contract and another 30 percent reporting that they are currently in negotiations.[6]

PhRMA worked with Avalere Health to analyze formulary coverage for existing outcomes-based contracts. Aetna and Harvard Pilgrim have announced outcomes-based contracts with biopharmaceutical manufacturers for several newer medicines for diabetes, high cholesterol and HIV. For the medicines included in these contracts, patient copays from 2015 through 2017 silver-level exchange plans were 28 percent lower, on average, for medicines when covered by the payers with outcomes-based contracts compared to the market average silver-level exchange plan (**Figure 4**). While it is not clear whether the silver-level exchange plan population was included in the payers' outcomes based-contract, this finding suggests that outcomes-based contracts can contribute to reduced cost sharing for patients.

Figure 4. Outcomes-Based Contracts Associated with Copayment Lowering Effect*



*Formulary analysis of 2015-2017 Silver level plans to examine tier placement, cost sharing and utilization management was conducted in April 2017 using Avalere Health PlanScape®, a proprietary analysis of exchange plan features. Formulary data is licensed from Managed Markets Insight & Technology, LLC.

Future Value-Based Contracts Can Potentially Generate Savings by Reducing Medical Costs

There is a tremendous opportunity to improve the use of medicines for many chronic conditions. For example, the American Diabetes Association estimates that the direct medical impact of diabetes is $176 billion dollars annually in the United States.[8] This impact includes 26.4 million hospital inpatient days, 7.8 million hospital outpatient visits and 7.3 million emergency department visits. Diabetes also increases workplace absenteeism, reduces workplace productivity and prevents individuals from being able to work, resulting in $69 billion in reduced productivity costs in addition to the direct medical costs.[9] Payers recognize the opportunity this presents and are interested in entering into value-based contracts for diabetes medicines. Of payers who have entered into an outcomes-based contract, 55 percent report that they have entered into a contract focused on endocrine disorders such as diabetes and an additional 33 percent are considering doing so.[6]

If new value-based contracts are able to improve use of medicines for diabetes and reduce the burden of this disease in the United States by as little as five percent, these contracts could save nearly $9 billion annually in direct medical costs by preventing 365,000 emergency department visits, 390,000 hospital outpatient visits and 1.3 million hospital inpatient days.[10] An additional $3.4 billion dollars would be gained from improvements in productivity for a total savings of over $12 billion annually.[11]

If, by improving the use of medicines, new value-based contracts can reduce the burden of diabetes in the United States by as little as five percent, these contracts could save **$12 billion** and prevent **365,000** emergency department visits, **390,000** hospital outpatient visits and **1.3 million** hospital inpatient days annually.

Conclusion

Value-based contracts appear to benefit patients through reduced cost sharing for some medicines. However, because many barriers to these contracts exist, we cannot judge the potential of value-based contracts by looking at those in the market today. Small policy changes to modernize outdated regulations have the potential to lead to tremendous benefits for patients and the health care system.

Sources

[1] PhRMA. "Barriers to Value-Based Contracts for Innovative Medicines: PhRMA Member Survey Results," 2017. Available at: https://www.statnews.com/wp-content/uploads/2017/03/PhRMA_ValueBased_MemberService_R23.pdf

[2] Ward AS et al. "Regulatory, Legal Uncertainties Are Barriers to Value-Based Agreements." Health Affairs Blog. November 4, 2016. Available at: https://www.healthaffairs.org/do/10.1377/hblog20161104.057443/full/

[3] Nazareth T, Ko JJ, Sasane R, Frois C, Carpenter S, Demean S, Vegesna A, Wu E, Navarro RP. Outcomes-Based Contracting Experience: Research Findings from US and European Stakeholders. Journal of managed care & specialty pharmacy. 2017 Oct;23(10):1018-26.

[4] Carlson JJ, Sullivan SD, Garrison LP, Neumann PJ, Veenstra DL. Linking payment to health outcomes: a taxonomy and examination of performance-based reimbursement schemes between healthcare payers and manufacturers. Health policy. 2010 Aug 1;96(3):179-90.

[5] Congressional Budget Office (CBO). Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services. 2012. Available at: https://www.cbo.gov/sites/default/files/112th-congress-2011-2012/reports/MedicalOffsets_One-col.pdf

[6] Avalere Health. Payer Perspectives on Outcomes Contracting. May 22, 2017.

[7] Garrison LP, Kamal-Bahl S, Towse A. Toward a broader concept of value: identifying and defining elements for an expanded cost-effectiveness analysis. Value in Health. 2017 Feb 28;20(2):213-6.

[8] The American Diabetes Association. The Cost of Diabetes. http://www.diabetes.org/advocacy/news-events/cost-of-diabetes.html.

[9] American Diabetes Association. Economic costs of diabetes in the US in 2012. Diabetes care. 2013 Apr 1;36(4):1033-46. https://doi.org/10.2337/dc12-2625

[10] Diabetes-related health care expenditures and resource utilization calculated as five percent of (1) $175.8 billion in medical costs, (2) 7.3 million emergency department visits, (3) 7.8 million hospital outpatient visits and (4) 26.4 million hospital inpatient days.

[11] Improvements in productivity calculated as five percent of $68.6 billion in annual productivity losses attributable to diabetes. Total savings calculated as: $244.4 billion * 5% = $12.22 billion.

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