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Will Trump Adopt Pharma’s Proposals on Value-Based Pricing? *Industry’s version of ‘paying for value’ raises red flags*

Reports indicate that one of the policies under consideration by the Trump Administration “Drug Pricing and Innovation Working Group” is “[v]alue-based pricing, wherein prescription drug corporations, “keep the list prices of drugs unchanged, but offer rebates if patients don’t improve.”¹

Types of value-based pricing

When prescription drug corporations talk about value-based contracts, it generally means that corporations should be able to charge even higher prices for drugs that show some demonstrable benefit as well as potentially weakening Medicaid limits on pharma profiteering.

But the term ‘value-based pricing’ can represent several very different policies in the pharmaceutical field. Those policies include:

- outcomes-based purchasing contracts—also known as risk-sharing or performance contracts—which condition payments on the volume of individuals that actually benefit from the drug; typically, a prescription drug corporation grants a larger rebate when evidence demonstrates the product is less effective, and a smaller rebate when evidence demonstrates that the product is more effective in a particular patient or patient population.
- indication-based pricing, which differentiates payment for a prescription drug based on the disease indication and relative benefit to the patient for that indication;
- comparative effectiveness of a drug, which usually establishes a benchmark price relative to the quality of life or benefit conferred by the drug; and
- reference pricing, where pricing is anchored to the most effective drug in a set of therapeutically similar drugs.

The utility of value-based pricing depends on the specific policy applied and the details of that policy. For example, reference pricing has been shown to significantly decrease both payer and patient expenditures,² while outcomes-based purchasing contracts have had minimal impacts, as discussed further below. The impact of indication-based pricing appears to vary widely in Europe and is usually used in conjunction with a larger nation-wide discount program.³ Comparative effectiveness has generated savings but raises concerns that imposing an arbitrary financial threshold would limit access to prescription drugs, particularly for cancer and rare diseases.⁴ Other reforms should be used in concert with comparative effectiveness data to ensure patient access is not impaired.

Prescription drug corporation influence in the Trump Administration

Reports suggest that President Trump’s draft Executive Order to address drug pricing through value-based payments presents a capitulation to PhRMA, the industry group representing prescription drug corporations.⁵ Following a meeting with President Trump on January 31st, Stephen Ubl, president and CEO of PhRMA, noted support for outcomes-based contracts as an alternative to the government negotiation of prices.⁶

The Trump Administration's reported selection of Joe Grogan⁷ to lead the working group raises concerns that any proposal on value-based pricing is likely to accord with the preferences of prescription drug corporations. Grogan currently serves as associate director for health affairs at the Office of Management and Budget (OMB)¹, but had previously acted as the head of federal affairs for Gilead Sciences² from 2011 through March of this year.⁸

Further suggesting that a value-based pricing proposal coming out of the Administration will be heavily influenced by the prescription drug industry, Grogan reportedly invited Robert Shapiro to brief the working group on value-based pricing in May.⁹ Shapiro is now Chairman of Sonecon, LLC, where he has advised Amgen, Gilead Sciences, PhRMA and the U.S. Chamber of Commerce.¹⁰

In recent months, HHS Secretary Tom Price has also held drug pricing listening groups with pharmaceutical and medical device corporations.¹¹ The Administration has demonstrated a proclivity for pursuing policies that benefit both groups –the American Health Care Act (AHCA) includes tax breaks of a combined \$50 billion for the two industries.¹²

PhRMA's flavor of value-based pricing

When prescription drug corporations refer to value-based pricing, they are often referring to outcomes-based purchasing contracts – preferably within a lax regulatory environment likely to provide financial rewards without risk. PhRMA advocates for outcomes-based payment in the context of potential weakening of price-reporting rules, increased off-label promotion of drugs, and the lowering of regulatory standards to approve drugs.^{13, 14} Under those circumstances, Medicaid prescription drug cost-controls could be weakened and standards for safety and efficacy information that doctors rely on would be lowered. The problem is compounded when prescription drug corporations promote most heavily the drugs with the lowest clinical value to patients.¹⁵

Pharmaceutical corporations previously have staunchly opposed value-based pricing initiatives that could produce actual savings in Medicare Part B.¹⁶ The Obama Administration last year proposed a demonstration that would have tested numerous value-based pricing approaches to reduce Medicare Part B prescription drug spending.¹⁷ Phase I of the proposed reforms would have reduced physicians' incentives to prescribe higher priced physician administered drugs; Phase II included value-based pricing reforms like reference drug pricing and bundled payments for episodes of care.¹⁸ Secretary Tom Price is on record opposing these reforms that would have reduced the \$22 billion spent on Medicare Part B.¹⁹ That initiative was opposed by PhRMA,²⁰ and Public Citizen analysis revealed that at least 75% of patient groups opposing the initiative received funding from prescription drug corporations.²¹

¹ Joe Grogan does not have a White House ethics waiver. It would seem that he is not in compliance with President Trump's Executive Order 13770, which calls for appointees who are former lobbyists not to engage in policymaking relating to the subject matter that the appointee recently lobbied on. See Craig Holman & Alex Brown. The Company We Keep: Lobbyists and the Prevalence of Conflicts of Interest in the Trump Administration. Public Citizen. (June 22, 2017). https://www.citizen.org/system/files/case_documents/2017_lobbyist_report_final_0.pdf

² In 2013, during Grogan's tenure as the Head of Federal Affairs, Gilead Sciences released a new hepatitis C drug, Sovaldi, with a list price of \$84,000 per 12-week course of treatment. A Senate Finance Committee investigation found that a key consideration for Gilead in pricing Sovaldi was to "maximize revenue," and "prepare the market for Harvoni and its even higher price." To date, the company has made \$50 billion in hepatitis C drug sales. See Committee on Finance. The Price of Sovaldi and Its Impact of the U.S. Health Care System. U.S. Senate. (Dec. 1, 2015)[https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)

Weakening patient access & anti-corruption laws

Value-based pricing proposals from prescription drug corporations threaten to weaken the power of state Medicaid programs to get the ‘best price’ for low-income individuals and undermine anti-kickback laws,²² while independent analysis suggests that implementing outcomes-based contracts would not warrant changes to the Medicaid best-price rule or the anti-kickback statute.²³

Current statutes and regulations ban illegal rebates, kickbacks, and bribes to prevent fraud and abuse.²⁴ Between 1991 and 2015, drug companies entered into 373 settlements totaling \$35.7 billion in criminal and civil penalties.²⁵ Forty-seven of those settlements involved companies paying kickback payments to healthcare providers and pharmacy benefit managers (PBMs) to change prescribing behaviors. Instead of a physician deciding whether to prescribe a drug to a patient based on clinically relevant information, companies spent billions in kick-backs, gifts, and detailing to increase sales.

PhRMA has recommended expanding “safe harbors” from enforcement regarding paying kickbacks to buyers (e.g. hospitals, insurers, individual physicians) to increase the utilization of value-based contracts. Their current proposal would widen the discount, personal services, and managed care safe harbors to include arrangements that provide incentive for increased use of a prescription drug regardless of its clinical value and weaken the regulatory disclosures of the terms of these confidential contracts (i.e. what buyers must do to get discounts or rebates).²⁶

The proposal could open the door to greater undue pharma influence on prescribing decisions. For example, Johnson & Johnson incentivized Omnicare, a nursing home pharmacy, to increase prescriptions of risperidone (brandname Risperdal) to elderly patients on the basis of market share rebate payments, data-purchase agreements, “grants” and “educational funding”. In 2013, the corporations settled \$2.2 billion in criminal fines and civil penalties for paying kickbacks to Omnicare and hiding evidence that Risperdal increased the risk of stroke in elderly patients.²⁷

Another 105 of those companies’ settlements related to the unlawful promotion of prescription drugs.²⁸ Off-label promotion expands the number of disease indications for which a drug can be reimbursed, often with little clinical evidence of safety or effectiveness. Recently, PhRMA has advocated that despite statutory prohibitions, they should be allowed to promote prescription drugs to healthcare payers before FDA approval, contrary to the health and safety interests of patients.²⁹

Other PhRMA proposals include exempting value-based payments from the Medicaid “best-price rule.” Currently, any rebates or discounts offered to private payers must be incorporated into the “best price” calculation i.e. the lowest price available to a healthcare payer on the market.³⁰ The statutory rebate offered to Medicaid is then calculated as the greater of either 23.1 percent or the difference between the average manufacturer price and “best-price.”³¹ Evidence suggests that the best-price rule is not a serious impediment to development of outcomes-based contracts.³² However, changes to the calculation of average manufacturer price (AMP) and best price are warranted to ensure that best price reflects actual net prices in the private market, including those received by PBMs.³³ There is no evidence to suggest that such a positive change is under consideration by the Administration.

No evidence that contracts increase competition or significantly decrease prices

The experience of the Italian healthcare system suggests that outcomes-based reimbursement also brings minimal savings to health programs. Examining twenty-five drugs, the Italian government was only able to claw-back around five percent of the initial revenue spent on the drugs.³⁴ Moreover, authors of the study found that risk-sharing agreements that refer to clinical outcomes were more

difficult to establish, and that the costs of hospital consultants' and pharmacists' time are likely to be considerable.³⁵ Further, the Netherlands ceased using outcomes-based contracting for oncology drugs after outcome evaluation failed due to poor data quality.³⁶

The proposed Executive Order notably does not address barriers to effective implementation of outcomes-based agreements, including measurement challenges, implementation costs, and the extremely fragmented healthcare system in the U.S.³⁷ Compared to other countries, the U.S. in particular lacks a robust and integrated electronic healthcare record system;³⁸ and in terms of long-term outcomes, annual individual turnover between employers and insurers is high.³⁹

The solution

Public Citizen supports a wide array of reforms that increase the quality of and access to affordable, lifesaving medicines. If the Trump Administration's Executive Order call for federal health programs to "enter into reimbursement arrangements for medical products that are based on the value of such products" is indeed a nod to the prescription drug corporation vision of outcomes-based contracts, as available information suggests, then this proposal falls short, providing extremely limited potential for relief and considerable burdens for implementation.

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- ⁸ <https://www.linkedin.com/in/joe-grogan-81b7845>
- ⁹ Kopp. Exclusive: White House Task Force Echoes Pharma Proposals.
- ¹⁰ *Ibid.* Also see Shapiro's CV, available at: <http://docs.house.gov/meetings/IF/IF16/20151027/104110/HHRG-114-IF16-Bio-ShapiroR-20151027-U1.pdf>
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²⁸ *Id.*

²⁹ See 21 U.S.C §§ 352(a), 321(n); *see also* PhRMA, *supra* note 12; Open Letter to U.S. House of Representatives' Energy and Commerce Committee. (June 5, 2017). <https://www.citizen.org/sites/default/files/2371.pdf>

³⁰ 42 U.S.C. § 1396r-8(c)(1)(C)

³¹ 42 U.S.C. § 1396r-8(c)(1)(A)(ii); *see also* 42 U.S.C § 1396r-8(c)(1)(B)(i)(VI)

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