



Fact Sheet: Trump Administration Proposes to Lower Drug Costs by Targeting Backdoor Rebates and Encouraging Direct Discounts to Patients

The Department of Health and Human Services Secretary Alex Azar and Inspector General Daniel Levinson have proposed a regulation that would create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs. This proposal has the potential to be the most sweeping change to how Americans' drugs are priced at the pharmacy counter, ever, by delivering discounts directly to patients at the pharmacy counter and bringing much-needed transparency to a broken system.

The proposed regulation would address a perverse incentive identified by the Department by expressly excluding from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations. The proposal would create a new safe harbor protecting discounts offered to patients at the pharmacy counter. Finally, the proposal would create new safe harbor protection for fixed fee services arrangements between manufacturers and PBMs.

The President's drug pricing blueprint identified how the current rebate-based system rewards higher list prices, enriches middlemen, and drives up patients' costs. Now HHS is taking action to encourage the drug industry to shift away from the opaque rebate system, and toward a system that offers true discounts to the patient at the point of sale.

Point of sale discounts will lower out-of-pocket costs for patients using drugs with high prices and high rebates, particularly during the deductible or coinsurance phases of their benefits. This proposal aims to change the incentives in our system that reward list price increases.

WHAT'S WRONG WITH TODAY'S SYSTEM

The current rebate-driven system is part of an unacceptable status quo characterized by high prices and backdoor deals. It creates three main problems for patients:

1. Rebates reward ever-increasing list prices. Everyone in today's system, including PBMs and Part D plans, typically negotiate rebates as a percentage of list price. When list prices rise, everyone benefits but taxpayers and the patients paying for the drug.

PBMs play an important role in negotiating with drug companies. But if the negotiation favors higher rebates instead of lower cost drugs, it can lead to higher list prices. Indeed, nearly every drug company taking a January 2019 price increase announced that all or nearly all of the increase was being paid to PBMs or insurers as rebates.

A system that favors higher list prices hurts patients, who often pay a percentage or all of the list price. It also drives up total spending for plans and payers.



By proposing to re-design the AKS safe harbors to protect upfront discounts, this proposal, if finalized, would counteract the incentives behind rising list prices. Drug companies would no longer be able to cite their rebate contracts as an excuse to keep raising list prices.

2. Drug companies pay rebates and other payments to PBMs, but these payments are not reflected in patient out-of-pocket drug costs. The average difference between the list price of a drug and the net price after a rebate is 26 to 30 percent. These rebates, negotiated in Medicare Part D and private plans, are typically not used to reduce patients' cost sharing for a particular drug.

- If the patient is spending out-of-pocket up to their deductible, they typically pay a drug's list price.
- If a patient is paying co-insurance, as is common for expensive specialty drugs, they typically pay it as a percentage of a drug's list price, even if the plan received a rebate.
- Patients with high out-of-pocket costs don't see the benefit of rebates when they pay for their prescriptions.
- In some cases, a patient's co-pay can actually be higher than the net price paid by the health plan after rebates.

By proposing to amend the safe harbor regulations to offer protection for reductions in price that are reflected at the point of sale, the proposal, if finalized, would provide a strong incentive for drug manufacturers to offer discounts that will directly benefit patients by lowering their out-of-pocket costs at the pharmacy counter.

3. The current rebate system discourages the use of safe, effective lower-priced generics and biosimilars.

A growing number of Part D plans have moved generic drugs to non-preferred tiers, and we have yet to realize the potential of biosimilar competition for high-cost biologics. Too often, this is because insurers and Part D plan sponsors can extract higher rebates for brand drugs and biologics.

At the same time, manufacturers of brand drugs and biologics can prevent generic or biosimilar competition by increasing the size of the rebates they pay for a drug or group of drugs, and condition the payment of those rebates on maintaining their exclusive formulary position. This makes it easier for PBMs and insurers to collect bigger rebates on already-existing sales volume than it is to lower drug spending by using lower costs drugs.

Excluding rival drugs with "rebate walls" or "bundled rebates" distorts our free market system, discourages generic competition and biosimilar adoption, and causes patients to pay more out of pocket.

WHAT THIS MEANS FOR PEOPLE WITH MEDICARE



Replacing safe harbor protections for opaque rebates with transparent discounts is expected to lead to lower Part D spending for Medicare beneficiaries as a whole, because the projected reductions in out-of-pocket costs are larger than potential increases in premiums.

By removing the incentives that reward list price increases, patients who have out-of-pocket costs based on list price will save. This includes patients who are spending through a deductible, using a drug not covered by their insurance, or who pay co-insurance that is tied to the list price.

If drug companies offer discounts directly to the consumer, patients will save at the pharmacy counter.

A large share of beneficiaries would benefit from such changes. Nearly one-fourth of Part D plans require beneficiaries to pay coinsurance for preferred brand drugs, and almost all use coinsurance for non-preferred brand drugs. Lower list prices and upfront discounts translate to beneficiary savings during the deductible, coinsurance, and coverage gap phase of the benefit.

Individual savings will vary based on annual drug costs and type of drugs they take, but sicker beneficiaries or those with higher drug costs are most likely to save the most. The new system would work as insurance is intended to: where those with especially high out-of-pocket drug costs will be most likely to benefit.

An estimated 30 percent of Part D beneficiaries have drug costs high enough that their out-of-pocket savings will likely exceed any premium changes. These are generally seniors who use expensive drugs, which often require co-insurance paid as a percentage of list price.

However, if Part D plans choose to cover more generics, improve negotiation with drug companies, or reduce overhead costs, premiums could be held constant and savings could be even greater.

WHAT THIS MEANS FOR PRIVATE PLANS

Longstanding OIG rules exclude from safe harbor protection price reductions offered to one payor but not to Medicare or Medicaid, particularly when such discounts serve as inducements for the purchase of federally reimbursable products. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business. This concern would extend to certain pharmaceutical rebate arrangements.

This rule exercises HHS' regulatory authority to address the rebate system as it relates to federal healthcare programs. Congress has more power to prohibit rebates in commercial insurance.

The National Business Group on Health recently surveyed large employers and found 3 in 4 employers do not believe drug manufacturer rebates are an effective tool for helping to drive



down pharmaceutical costs and over 90% would welcome an alternative to the rebate-driven approach to managing drug costs.

HOW THE PROPOSAL WOULD WORK

This proposal would update the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs, Part D, and Medicaid managed care plans from the safe harbor's definition of a "discount." It would also create a new safe harbor designed specifically for price reductions on pharmaceutical products, but only those that are reflected in the price charged to the patient at the pharmacy counter.

The proposal carries out Congress' directive to identify legitimate and beneficial payment practices that should not be subject to prosecution under the AKS, and its expectation that the safe harbor rules would be periodically evaluated and updated to reflect changes in health care delivery and payment practices.

The discount safe harbor as it exists today has evolved to protect both up-front discounts to buyers, as well as "delayed" discounts, or rebates, that are paid to a buyer some time after the sale. While rebates can function like legitimate reductions in price, the use of rebates in the prescription drug supply chain has had increasingly pernicious effects. And to the extent that these rebate payments are made to secure preferential formulary treatment, they are not functioning like a reduction in price.

The current discount safe harbor has not been updated since the establishment of the Medicare Part D program, and the regulations we are proposing today are designed to specifically address, for the first time since implementing the Part D program, certain payment arrangements among participants in the prescription drug supply chain.

The proposed rule would advance the President's promise outlined in the Administration's blueprint for lowering drug prices and putting American patients first – specifically the intent to investigate "measures to restrict the use of rebates, including revisiting the safe harbor under the anti-kickback statute for drug rebates."

PART OF THE PRESIDENT'S BLUEPRINT

Replacing the rebate system with upfront discounts for patients was one of the ideas put forth in President Trump's "[American Patients First](#)" blueprint for lowering prescription drug prices and out-of-pocket costs. Today's proposal will also enhance other key ideas from the blueprint that have already been implemented or are in the process of implementation, including:

- Providing new tools for Medicare Part D plans to negotiate deeper discounts for patients, which under today's proposal will be directly reflected in patients' cost-sharing.
- Requiring television advertisements for prescription drugs to disclose the drug's list price, which is currently used to calculate many patients' cost sharing and is expected to



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more closely resemble many drugs' total net cost after the implementation of today's proposal.

- Cutting down on practices that impede the approval and marketing of generic drugs and biosimilars, which are expected to be made more competitive by the replacement of rebates with upfront discounts.