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Contact: HHS Press Office
202-690-6343
media@hhs.gov

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

Directed by President Trump's July 24, 2020 Executive Order on "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen," the Department of Health and Human Services Secretary Alex Azar and the HHS Office of Inspector General (OIG) have finalized a regulation that encourages lower list prices and reduced out-of-pocket spending on prescription drugs.

This regulation addresses a perverse incentive identified by the Department, by expressly excluding rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs) and Part D plans from safe harbor protection under the Anti-Kickback Statute (AKS). The rule creates a new safe harbor protecting discounts reflected in the price of the drug at the pharmacy counter. Finally, the rule creates new safe harbor protection for fixed-fee services arrangements between manufacturers and PBMs.

The President's May 2018 drug pricing blueprint identified how the current rebate-based system rewards higher list prices, enriches middlemen, and drives up patients' costs. Now, Secretary Azar is taking action to encourage the drug industry to shift away from the opaque rebate system, and toward a system that offers true discounts reflected 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 rule changes 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 re-designing the AKS safe harbors to protect upfront discounts, this rule counteracts the incentives behind rising list prices. Drug companies will 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 nearly 30 percent for brand drugs. 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 pay the amount agreed to between the plan and the pharmacy, usually based in some way on the drug's list price and not taking into account rebates to plans.
- If a patient is paying co-insurance, as is common for expensive specialty drugs, they pay it as a percentage of the amount agreed to between the plan and the pharmacy, usually based in some way on the drug's list price, and whether the plan received a rebate does not typically affect the price.
- In some cases, a patient's cost sharing alone can actually be higher than the net price paid by the health plan after rebates.

By amending the safe harbor regulations to offer protection for reductions in price that are reflected at the point of sale, the rule provides a strong incentive for drug manufacturers to offer discounts that directly benefits Medicare patients by lowering their out-of-pocket costs at the pharmacy counter and eliminates the perverse incentives for ever higher list prices for all patients.

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.

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" distorts competition, discourages generic use 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 that must instead be reflected in the price at the pharmacy counter, patients will save.

A large share of beneficiaries will benefit from such changes. 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 will work as insurance is intended to: where those with especially high out-of-pocket drug costs will be most likely to benefit.

The Department believes that Part D plans are likely to choose to cover more generics, improve negotiation with drug companies, and reduce overhead costs in order to hold premiums constant, making savings even greater—as laid out in the President's July Executive Order, which directed that the final rule will not increase premiums. In reaching this conclusion, the Secretary has reviewed analyses prepared by the Office of the Actuary (OACT) at the Centers for Medicare & Medicaid Services (CMS) and the White House Council of Economic Advisors (CEA), as well as outside expert opinions, including those of Milliman, a highly respected international actuarial and benefit analysis firm that advises many of the nation's health insurers on the design and financing of pharmacy benefits. These analyses are included in the rule.

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 - PDF" blueprint for lowering prescription drug prices and out-of-pocket costs. As Secretary Azar said in announcing the blueprint, "We believe that the entire system of pharmacy benefit managers negotiating rebates needs to be re-examined. Right now, we're asking a pretty

straightforward question: What if, instead of the current system where drug companies get paid rebates and middlemen take a cut, we just had fixed-price discounts? This would fix the situation where even the pharmacy benefit manager, who is hired to help keep prices low, makes money from higher list prices."

Today's rule also enhances 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 rule will be directly reflected in patients' cost-sharing.
- 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.

WHAT THIS MEANS FOR PRIVATE PLANS

Longstanding OIG guidance explains that price reductions offered to one payor but not to Medicare may implicate and may violate the Anti-Kickback statute by disguising remuneration for federal healthcare program business through the payment of amounts purportedly related to non-federal healthcare program business. This concern extends to certain pharmaceutical rebate arrangements.

This rule exercises the Department's regulatory authority to address arrangements subject to the AKS, which is limited to federal healthcare programs. Congress has more power to prohibit rebates in commercial insurance.

The National Business Group on Health 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 more than 90 percent will welcome an alternative to the rebate-driven approach to managing drug costs.

HOW THE RULE WORKS

This rule updates the discount safe harbor at 42 CFR 1001.952(h) to explicitly exclude reductions in price offered by drug manufacturers to PBMs and Part D plans from the safe harbor's definition of a "discount." It also creates 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 rule carries out Congress's 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 will 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 sometime 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.

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 finalized rule advances 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."

The draft rule was proposed on January 31, 2019. The Department never withdrew the proposal from consideration and is finalizing the proposal today in a way which addresses the comments received.

HOW IS THE FINAL RULE DIFFERENT FROM THE PROPOSED?

The following are the major changes made to the final rule.

- **Effective Date**

  - The most impactful change we made from the Proposed Rule to the Final Rule is to finalize an effective date of January 1, 2022 instead of January 1, 2020 for the revisions to the discount safe harbor (42 C.F.R. § 1001.952(h)). Our proposal to make these changes effective on January 1, 2020 generated a large number of comments, highlighting many reasons that this effective date would be difficult, if not impossible, for some entities. By finalizing a date of January 1, 2022, entities have well over a year to make any necessary changes to their business arrangements. We expect this change, which has considerable substantive significance (i.e., with regards to implementation timeframe), to be well-received by stakeholders.

- **Formulary Placement**

  - We clarify in this Final Rule that reductions in price offered to Part D plan sponsors or Medicaid MCOs contingent on formulary placement can be protected under the new point-of-sale reductions in price safe harbor at 42 C.F.R. § 1001.952(cc), and reductions in price offered to Medicaid MCOs contingent on formulary placement were and continue to be protected by the discount safe harbor at 42 C.F.R. § 1001.952(h).

- **Medicaid Managed Care Organizations (MCOs)**

  - We are not moving forward with our proposal to amend the discount safe harbor (42 C.F.R. § 1001.952(h)) to exclude rebates offered to Medicaid MCOs. In other words, rebates offered from pharmaceutical manufacturers directly to Medicaid MCOs can still be protected by this safe harbor if all conditions of the safe harbor are met. We expect this change to be well-received by stakeholders.

- Medicaid MCOs will be able to use the new safe harbor for point-of-sale reductions in price for prescription pharmaceutical products (42 C.F.R. § 1001.952(cc)).

- **Chargeback Process**

  - We make clear that the Department is agnostic as to which entities (*e.g.*, PBMs, wholesalers) administer the chargeback function and we do not prescribe any requirements regarding chargeback administration arrangements.

  - We are finalizing certain revisions to the proposed definition of "chargeback."

    - First, in response to commenters, we are renaming it a "point-of-sale chargeback."

    - We proposed to define a "chargeback" as a payment from a manufacturer to a dispensing pharmacy that would be at least equal to the discounted price of the drug agreed to by the manufacturer and the Part D Plan sponsor or Medicaid MCO. We agree with commenters who noted that our proposed definition could lead to gaming and that the chargeback should be equal to the reduction in price, not the discounted price of the drug, so we define a chargeback in the final rule as a payment equal to the reduction in price. This definition ensures that the pharmacy is made whole for the difference between acquisition cost, plan payment, and beneficiary out-of-pocket payment.

WHY NOW

Back in July, the President directed, through an Executive Order with the aim of Lowering Prices for Patients by Eliminating Kickbacks to Middlemen, that we finalize this rule. Since then the team at HHS and OIG have worked to get the rule ready for publication today.

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