Trump/HHS Proposed Plan to Change Rebates

In February, HHS proposed a new rule intended to curtail climbing prices of prescription drugs. The plan seeks to **overhaul the use of rebates to Medicare Part D plans (PDP) and Managed Medicaid**, shifting the financial structure of rebates to benefit patients. While currently in the process of review, the implications may markedly change the model of healthcare in the U.S.

Proposed Plan	*Explanation*
Exclude rebates paid by manufacturers to PDPs and Medicaid MCOs from safe harbor protection	• The law would classify **rebates offered to PBMs** affecting government plans as kickbacks, and therefore **illegal**
Create a new safe harbor for prescription drug discounts offered at point-of-sale	• Shifts the recipient of rebates to **patients at the point-of-sale** by creating discount-chargebacks **calculated from rebates in-real time**
Create a new safe harbor for fixed fee service arrangements between manufacturers and PBMs	• Fee arrangements are currently based on a percent of WAC or rebates, thus the plan would move fees towards a **fixed model for PBM services**

Key issues that HHS has identified with the PBM rebate model and potential counter arguments:

Identified Issues	*HHS Explanation*	*Counter Arguments*
Rebates may drive list price growth	• Increasing rebates are a key factor driving list price inflation from manufactures protecting their bottom line	• Manufacturer contracts with PBMs often include price protection terms **that limit the impact of list price increases** • Historically, there have been **large list price increases for highly rebated drugs** and lower or **non-rebated drugs**
PBM rebating may inflate federal spend	• Medicaid may be deprived of larger rebates since rebates, discounts, or other transactions from manufacturers to PBMs may not be considered in 'Best Price'	• **Medicare Part D rebates, if greater than 23.1% , would decline if included in best price** calculations for Medicaid • **Medicaid savings** from inclusion of Part D in best price calculations **may not exceed Part D losses** from lower rebates
Rebates are not shared with patients	• List price increases primarily affect patients as co-insurance is generally calculated off list-prices and rebates are not consistently passed through	• **Nothing statutorily prevents plans from sharing rebates with patients** and select plans have passed through savings at point-of-sale (e.g., UnitedHealthcare) • **Plans voluntarily choose to set co-insurance based on list prices** instead of net price and could choose flat copays
Rebating creates problematic incentives for formulary management	• Formulary status and management may be driven by rebate depth and not by therapeutic value	• Removing **PBM fees tied to rebates may eliminate their incentive to negotiate lowest net price** for their customers • In the absence of rebates, **management will still be driven in part by cost** (e.g., lowest list, or net-price after chargeback)

The Bottom Line

While this proposed policy is intended to address **the rising cost of drugs**, it essentially replaces rebates with point-of-sale charge-backs as the primary means of negotiating lower prices.

The plan **may actually reduce competition** among drug manufacturers if their net price concessions (via charge-back) become more transparent to customers. Furthermore, it **does not improve the ability of Medicaid or Medicare programs to negotiate lower net prices,** and **does not guarantee that manufacturers will offer higher fixed-fee payments** to make up PBMs' losses.

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