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Eliminating pharmaceutical rebates: where do we go from here?

Significantly changing key elements of the US healthcare system can be effective and in the best interests of patients, but sometimes such changes are ill-advised. Presidents George W. Bush and Barack Obama were largely successful in implementing "radical" changes to the healthcare system, the former instituting a drug benefit for seniors through the Medicare Part D prescription drug program, the latter in extending healthcare options to the uninsured through the Affordable Care Act (ACA). In contrast, President Bill Clinton's first administration was tainted by its failure to implement an ambitious plan to reform the healthcare system. More than 20 years later, President Trump proposed another such sweeping change – elimination of manufacturer rebates to federally sponsored prescription drug plans, i.e., Medicare pharmacy benefits managers (PBMs) and Managed Medicaid – with the aim of lowering patients' prescription drug costs. After much public review, analysis and debate, the proposal was recently abandoned by the Trump Administration. So where do we go from here?

One of the Trump Administration's goals in proposing the rebate elimination plan was to reduce the potential for unintended incentives created by the protection of rebates under the safe-harbor provisions of the Anti-Kickback Statute (AKS). One such incentive is that PBMs may give preferential formulary coverage status to drugs with higher list prices to enhance their rebate revenue. While in the past, rebate revenue was often retained by the PBMs, the vast majority of rebates now flow back to health plans. Nevertheless, patient co-insurance payments for higher-cost specialty drugs are often based on list prices rather than net prices, i.e., the patients' payments are not based on the actual or "net" cost to the PBM or insurer after rebates.

Although the healthcare system is complex, one alternative proposal might accomplish the Administration's objective of lower patient costs without fundamentally altering the existing model. Under this proposal, more equitable patient co-insurance levels could be set based on average sales price (ASP). This would not require completely abandoning the PBM rebate model and price negotiation in setting formularies, and it would provide more transparency to patients and other stakeholders about the actual costs of their prescription drugs. Manufacturers already report ASP for Part B drugs; this mechanism could be extended to Part D drugs and it would ensure that patients pay co-insurance based on net cost after rebates, on average. This would also preserve PBM and insurer

discretion in setting formularies, continuing consideration of non-price factors (e.g. comparative efficacy of therapies, cost offsets, innovation).

One might argue that a more equitable approach would be to set patient co-insurance levels based on the costs actually paid by individual PBMs and insurers, i.e. plan-level net costs after rebates. While setting co-insurance levels based on individual plans' net costs would lead to greater price transparency, it would involve significant additional reporting requirements and administrative burden, and it is not certain that lower patient total cost of care would result. Moreover, it may result in more limited options for patients as formulary decision makers are pressured to focus increasingly on price alone, as opposed to accounting for the comparative efficacy of therapies, the ability to offset other healthcare costs, and the value of innovation. Although the current system of PBM rebates (and more generally rebate-driven formularies) has its issues, it is not clear that eliminating negotiated rebates, or complete transparency to net prices, would be in the best interest of patients if the goal is to lower patients' total cost of care while maintaining or improving quality of care and treatment options.

To conclude, completely eliminating PBM rebates is not critical for lowering patient drug costs. Setting co-insurance for high-cost specialty therapies based on average sales price (ASP) could lower patient co-insurance costs while providing greater price transparency, and is feasible to implement as ASP is currently reported for Medicare Part B drugs.

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