

Trump Administration Issues Proposed Rule to Dramatically Change Drug Rebates

On Thursday, January 31, 2019, the Trump Administration announced [a proposed rule](#) to eliminate rebates from drug manufacturers to pharmacy benefit managers (PBMs) in the Medicaid managed care and Medicare Part D programs. The proposed rule accomplishes this aim by removing safe-harbor protection[1] under the federal Anti-Kickback Statute (AKS)[2] for these rebates. In addition, the administration proposed new safe-harbor protections for rebates and other price reductions that will reduce the cost-sharing for patients when they purchase prescriptions and protect some flat PBM service fees (i.e. fees that are not tied to the price of the drug). As part of [the announcement](#), the Department of Health and Human Services said “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 Source has previously described [how these rebates evolved](#), and [how they caused a gross-to-net bubble](#) in which the list prices for drugs have little relation with the reimbursement rates actually paid by insurers and PBMs. The proposed rule aims to change the pharmaceutical pricing system so that prices are more transparent and patients directly benefit from discounts and rebates offered by the manufacturers. The magnitude of the impact of the proposed changes, however, remains unclear. As Rachel Sachs details in a [blog post for Health Affairs](#), the impact of these proposed changes are so dramatic that its specific effects on drug costs is difficult to predict. The administration is seeking comment on the likely impact of the proposed rule on out-of-pocket costs, premium costs, and overall government spending on these programs. Experts agree that under this proposed rule, the out-of-pocket costs for beneficiaries using specialty drugs will likely decrease, but all Medicare beneficiaries may see an increase in premium costs as insurers are no longer able to use drug rebates to offset premium costs.

While the relative size of these changes and the effect on government spending are still uncertain, The Source is optimistic about the changes. Specifically, they eliminate the financial incentive for manufacturers to increase the list price of a drug and then offer large rebates to PBMs for better placement on formularies. As The Source [previously described](#), these arrangements are particularly harmful to patients without insurance and those who must pay a percentage of the cost of specialty drugs. The newly announced proposed rule represents a meaningful and constructive step by the Trump Administration to [deliver on its promises from 2018's blueprint to reduce drug costs](#).

[1]42 CFR 1001.952(h)

[2]Social Security Act §1128B(b).