

Safe Harbor Protection Changes for Prescription Drugs and Pharmacy Benefit Managers

OVERVIEW

On January 31st, the Department of Health and Human Services (HHS) released a proposal to exclude certain rebates on prescription drugs from “safe harbor” protections under the Anti-Kickback Statute (AKS) of the Social Security Act.

The rule proposes an effective date of January 1, 2020. HHS will accept comments on the rule through April 1, 2019. The fact sheet can be found [here](#) and the full proposed rule can be found [here](#).

AKS and Safe Harbor Protections

The AKS prohibits anyone from knowingly offering, soliciting, or receiving payment in return for referrals or business reimbursable under any of the Federal health care programs. AKS violations are classified as felonies and are punishable by fines of up to \$100,000, imprisonment for up to 10 years, and/or civil monetary penalties. Due to the broad reach of the statute, Congress has required the development of safe harbor protections that allow certain “non-abusive” business practices to be exempt from criminal prosecution under the AKS.

With the protection of safe harbors, drug manufactures have been able to offer pharmaceutical benefit managers (PBMs), Part D plans, and Medicaid managed care organizations (MCOs) rebates for prescription drugs based on list price, volume, and market-share. HHS argues that this practice has led to increased drug pricing by incentivizing manufactures to increase list prices and PBMs to encourage the use of drugs with higher lists prices, which are generally associated with a higher rebate. Since rebates often do not trickle down to the consumer, the use of rebates has been associated with higher out-of-pocket spending for beneficiaries.

The proposed rule intends to tackle the misaligned incentives driving higher drug costs from manufacturers by encouraging a shift away from the rebate system in favor of discounts that lower the list price and thus the prices patients pay at the point-of-sale.

Proposed Changes

HHS is proposing to update the safe harbor definition of “discount” to explicitly exclude price reductions offered by drug manufacturers, such as rebates, to PBMs, Part D, and Medicaid MCOs for the sale or purchase of prescription pharmaceutical products, unless the price reduction is required by law (e.g. – Medicaid Drug Rebate Program rebates). HHS solicits comment on whether this exclusion should be limited to pharmaceutical products payable by Medicare Part D and Medicaid MCOs, or also apply to products payable under other HHS programs (e.g. – Medicare Part B).

HHS notes that discounts offered to other payers, including commercial payers, will continue to be excluded from the safe harbor provisions unless they are also offered to Medicare and Medicaid, which

would make offering exclusive discounts/rebates to any commercial payer at risk for AKS charges if it could be shown that they create an adverse impact for HHS programs.

Under the proposed rule, the discount safe harbor would continue to protect discounts on prescription drugs offered to other entities, such as hospitals, physicians, and pharmacies.

In removing the current safe harbor, HHS is proposing two new safe harbors in its place:

- **Point-of-Sale Discounts:** HHS proposes a discount safe harbor that would protect certain price reductions offered by drug manufacturers to Part D plans, Medicaid MCOs, or to PBMs if the reductions are applied at the point-of-sale for beneficiaries.
- **Protecting Certain PBM Service Fees:** HHS intends to protect certain fees that pharmaceutical manufacturers pay to PBMs for services rendered in the form of fixed-fee service arrangements. Under this protection, the fees would have to be for services that relate to the PBM's arrangements with health plans.

IMPACT ANALYSIS

The proposed rule includes analysis on the projected impact of implementing the rule. Actuarial analyses performed by the Office of the Actuary, Milliman, and Wakely found that while out-of-pocket costs to consumers are projected to decrease, federal spending and premiums are projected to increase. The actuaries offered different projections as to whether or not list prices would actually decrease as a result of the proposed changes.