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## PBMs

### HHS Secretary proposes closing of safe harbor for rebates paid by drug manufacturers to PBMs, Part D plans, and Medicaid MCOs

On January 31, HHS Secretary Alex Azar announced a proposed rule that would close current safe harbors under the Anti-Kickback statute that allow manufacturers to pay rebates to PBMs, Part D plan sponsors, and Medicaid managed care organizations. Instead, the rule would create a new safe harbor for rebates paid directly to patients or beneficiaries. The proposed rule was published in the Federal Register on February 6.

In the background to the rule, the Department used an example whereby a drug with a WAC of $100 is sold to the wholesaler for WAC less 2%, or $98. The wholesaler sells, in this example, the drug to the pharmacy for $100, and when it dispensed to a beneficiary of a Part D plan, the example pharmacy is reimbursed at the rate of “1.20 x WAC/list price minus 15% plus a $2 dispensing fee.” In the example, the pharmacy is paid $104. However, the plan sponsor benefits from a rebate negotiated by a PBM of 30% of the WAC, or $30. Thus, the plan sponsor pays $74 ($104 - $30) for the drug, but the price on which the patient’s co-pay is calculated is not reduced by the rebate. “Under the current rebate-based system, beneficiaries may not receive the benefits of reduced prices and costs that other parties do.”

In addition to this effect on the cost of drugs to beneficiaries, the Department asserts that the rebate-based system could be “skewing decisions on which drugs appear on a beneficiary’s drug formulary, and a drug’s placement on the formulary.” The background statement also suggests that “PBMs may favor drugs with higher rebates over drugs with lower costs, and ... [information has raised] new concerns about ‘bundled’ rebates discouraging the adoption of new, lower-cost brand drugs and biosimilars.”

In light of its concern that high list prices harm federal health care programs, and that the rebate system is not transparent, the proposal would amend the safe harbor in 42 CFR 1001.952(h) for discounts, by explicitly stating that “certain price reductions on prescription pharmaceutical products from manufactures to plan sponsors under Medicare Part D and Medicaid MCOs would not be protected under the safe harbor.” A new safe harbor would be created to “protect discounts ... if such discounts are given at the point of sale and meet certain other criteria.” Finally, a safe harbor will be created to allow for PBM “service fees” established at flat rates by which the PBM provides advice or services to the manufacturers “that relate in some way to the PBM’s arrangements to provide pharmacy benefit services to health plans.” As an example, the PBM might provide data to a manufacturer that would help prevent duplicate discounts for 340B drugs. [DHHS, OIG. 42 CFR Part 1001. Fraud and abuse; removal of safe harbor protection for rebates involving prescription pharmaceuticals and creation of new safe harbor protection for certain point-of-sale reductions in price on prescription pharmaceuticals and certain pharmacy benefit manager service fees. 84 Fed. Reg. 2340, February 6, 2019]