Removing or Limiting the Safe Harbors for Pharmaceutical Manufacturer Rebates Would Increase Costs to Patients and Payers

Federal officials have blamed the federal anti-kickback statute's safe harbors allowing manufacturers to pay rebates to health plans for the high cost of drugs and suggested that the safe harbors should be "reexamined." Statutory exceptions and regulatory safe harbors to the federal anti-kickback statute have been in place for decades and protect rebating to bring down the cost of drugs. Ending or limiting the safe harbors—thus subjecting pharmaceutical rebates subject to anti-kickback statute scrutiny--would leave patients and payers, including Medicare and Medicaid, at the mercy of drug manufacturer pricing strategies without sufficient tools to control costs.

Pharmaceutical Manufacturers Expanded Use of Rebates Following Settlement of a Class Action Lawsuit

- Drug manufacturers' expanded use of rebates for pharmacy-dispensed prescription drugs paid by insurers is the result of the settlement of a class action lawsuit. Tens of thousands retail pharmacies sued in the early 1990s, alleging price discrimination and conspiracy to illegally fix prices charged to hospitals and pharmacies.
- Under the settlement, manufacturers agreed to pay more than $408 million in damages and to offer the same types of discounts to all entities that could "demonstrate an ability to affect market share."
- Determining market-share movement can only be done retroactively through rebates. Up front discounts are not permissible under current anti-trust rules.
- Rebates allow manufacturers to segment the market – payers that move more market share get higher rebates, while payers moving no market share – individuals – pay list price.

Elimination of the Rebate Safe Harbor Would Tie the Hands of Payers

- Price concessions negotiated by PBMs, most of which are in the form of rebates, significantly lower the cost of drugs to insured patients.
- According to researchers, PBMs help patients and payers save $941 per enrollee per year in prescription drug costs.[1]
- Without the use of rebates, payers would have little ability to drive competition among brand drug manufacturers. Payers could negotiate neither up-front discounts nor after-the-fact discounts through rebates.
- It is illogical to think that manufacturers would simply lower their prices to all payers across the board in the absence of rebates.

Limiting Rebates Would Curtail Competition and Help Manufacturers

- If rebates were limited to a certain percentage of list price, that would also limit competition. Manufacturers would know they could raise prices and not be subject to competition beyond a certain point.
- If rebates were eliminated, PBMs and other payers could be forced to institute narrower formularies with more restrictions in order to attain reasonable costs.

States Relying on Medicaid Supplemental Rebates Could Lose Revenue

- 47 states rely on supplemental rebates for nearly $2 billion in additional revenue for Medicaid, funding that could be lost should safe harbors be revised.

Restricting rebates while statutorily requiring Medicaid rebates would be legally inconsistent and questionable

- By statute, brand manufacturers must pay the federal government 23.1 percent rebates for brand drugs used in Medicaid.

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[1] Visante, Inc. "The Return on Investment (ROI) on PBM Services," Prepared by Visante on behalf of PCMA, November 2016. https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf