

## **HHS Removes Discount Safe Harbor for Manufacturers and Adds Point of Sale and PBM Service Fee Safe Harbors**

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On Nov. 20, 2020, the United States Department of Health and Human Services finalized the proposed rule which altered the drug discount safe harbor under the Anti-kickback Statute. The Proposed Rule was initially published in Feb. 20, 2020, but was put on hold until President Trump's July 24, 2020, Executive Order directing the Secretary of Health and Human Services to complete the rulemaking process.

The final rule creates two new safe harbors for point-of-sale reductions in price and payment of PBM service fees by manufacturers.

With regard to the point of sale discount, the new safe harbor protects reductions in price on prescription pharmaceutical products offered to plan sponsors under Medicare Part D, Medicaid MCOs, or through a PBM acting under contract with either if: (1) the reduction in price is set in advance; (2) the reduction in price does not involve a rebate, unless the full value of the price reduction is accomplished through chargebacks or is a rebate required by law; and (3) the reduction in price is completely reflected in the price the pharmacy charges to the beneficiary at the point of sale. HHS was concerned that many discounts do not ultimately benefit consumers and that by requiring the reduction at the beneficiary level, the discount would ultimately lower the prices paid by consumers.

The final rule also added a safe harbor for fees paid by manufacturers to PBMs. HHS recognized that PBMs often provide legitimate services to manufactures that should be compensated. To qualify under the new safe harbor: (1) the services and compensation must be set out in a written agreement; (2) the compensation must be consistent with fair market value in an arm's-length transaction and be a fixed payment (i.e., not based on a percentage of sales) and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, or between the manufacturer and the PBM's health plans; and (3) the PBM must make annual written disclosures to each health plan with which it contracts regarding the services rendered to each pharmaceutical manufacturer related to the PBM's arrangements to furnish pharmacy benefit management services to the health plan, and make such disclosures to the secretary upon request.

Both new safe harbors go into effect Jan. 29, 2021.

The final rule also altered the discount safe harbor to exclude manufactures of prescription pharmaceutical products from the definition of discount price reductions in connection with the sale to plan sponsors under Medicare Part D, Medicaid MCOS, and PBMs acting under contract with plan sponsors under Medicare Part D or Managed Medicaid. The reason for the change was HHS's concern that such rebates do not ultimately benefit either consumers or the federal programs and, in some cases, these rebates encouraged use of list prices which ultimately raises costs of the products.

These changes to the current safe harbor, however, do not become effective until Jan. 1, 2022, to allow manufacturers to restructure their agreements.

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