

Publications

Health Care Alert: HHS Aims to Reduce Prescription Drug Prices Through Proposed Changes to the Anti-Kickback Statute's Safe Harbors; Comments Due April 8, 2019

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On February 6, 2019, the U.S. Department of Health and Human Services (HHS) published a [proposed rule](#) that would amend the "Discounts" safe harbor under the Anti-Kickback Statute and create two new safe harbors respectively protecting "Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products" and "PBM Service Fees."

The Anti-Kickback Statute and Safe Harbors

The federal Anti-Kickback Statute (AKS) makes it a crime to knowingly and willfully offer, pay, solicit, or receive "remuneration" to induce or reward the referral of items or services reimbursable by federal health care programs. Violations of the AKS are punishable by fines of up to \$100,000 and imprisonment for up to 10 years, as well as civil monetary penalties (CMPs), exclusion from federal health care programs, and liability under the False Claims Act.

Because the AKS' broad prohibition may cover even some legitimate arrangements, HHS recognizes certain defined "safe harbors" approving of instances of "remuneration" if certain requirements are met. Although the failure to comply with all requirements of an individual safe harbor is not automatically fatal under the AKS, arrangements implicating the AKS should be structured to satisfy as many elements of an appropriate safe harbor as possible.

Proposed Changes

Citing concerns that rebate arrangements between pharmacy benefit managers (PBMs) and drug manufacturers contribute to increased list prices and, as a result, higher costs for federal health care programs and their beneficiaries, HHS first proposes to amend the existing "Discounts" safe harbor to expressly exclude from protection certain price reductions from manufacturers to (1) Medicare Part D plan sponsors, (2) Medicaid Managed Care Organizations (MCOs), and (3) PBMs acting under contract with either of the foregoing. Specifically, the safe harbor would no longer protect price reductions offered by a manufacturer to any of the listed entities "in connection with" the sale or purchase of prescription pharmaceutical products, unless such reduction is required by law (for example, rebates under the Medicaid Drug Rebate Program). The proposed rule makes clear that the amendment is not intended to affect discounts offered to other entities (including, but not limited to, wholesalers, hospitals, physicians, pharmacies, and third-party payors in other Federal health care programs), nor other types of discounts (such as volume or prompt payment discounts to wholesalers) that otherwise satisfy the requirements of the existing "Discounts" safe harbor.

Second, HHS proposes to create a new safe harbor for “Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products.” This safe harbor – which could potentially apply to discounts offered by drug manufacturers to Part D plan sponsors, Medicaid MCOs, and/or their PBMs – would require that any reduction in price:

1. Be **set in advance**, meaning that the terms of the reduction would be fixed and disclosed to the Part D plan sponsor or Medicaid MCO by the time of its first purchase of the product at the reduced price;
2. **Not involve a rebate**, unless the full value of the reduction in price is provided to the dispensing pharmacy through a “chargeback”; and
3. Be **completely reflected in the price the pharmacy charges to the beneficiary** at the point of sale.

Importantly, like the existing “Discounts” safe harbor, this new safe harbor would exclude from protection price reductions offered to one payor but not to Medicare or Medicaid.

Finally, HHS proposes to create a second new safe harbor for “PBM Service Fees.” This safe harbor would protect payments from pharmaceutical manufacturers to PBMs for pharmacy benefit management services provided to the manufacturers if:

1. There is a **written agreement** between the PBM and the manufacturer that (a) covers all of the services the PBM provides to the manufacturer for the term of the agreement, and (b) specifies each of the included services and the compensation therefor;
2. Any compensation paid to the PBM is (a) **consistent with fair market value** in an arm’s-length transaction; (b) **fixed**, not based on a percentage of sales; and (c) not determined in a manner that takes into account the volume or value of referrals between the parties; and
3. The PBM **discloses in writing**, at least annually, to each health plan with which it contracts (a) the services rendered by the PBM to each pharmaceutical manufacturer that were related to the PBM’s arrangements with that health plan, and (b) the associated costs for such services.

Effective Dates and Comments

The proposed rule contemplates that the amendment to the “Discounts” safe harbor will take effect on **January 1, 2020**, but specifically solicits comments regarding whether a longer transition period will be needed. The proposed rule also solicits comments regarding (among other things) a definition for the phrase “in connection with” which would appropriately define the scope of the new exclusion.

The new safe harbors are expected to become effective 60 days after publication of the final rule.

If you have questions regarding the proposed changes, the comment submission process, or the Anti-Kickback Statute generally, please contact Matt Albers, Mairi Mull, or your regular Vorys attorney.