

# Proposed Rules Address Prescription Drug Pricing

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Last week, the Department of Health and Human Services (“HHS”) released a proposed rule to lower prescription drug prices and out-of-pocket costs by encouraging manufacturers to pass discounts directly to patients and bring new transparency to prescription drug markets.

Briefly:

- **Nothing has changed. This is a proposed rule.**
- Even if finalized in its current form, the proposed rule **does not impact employer-sponsored plans unless** Pharmacy Benefit Managers (“PBMs”) and pharmaceutical manufacturers adopt a new safe harbor (discussed below), which may provide additional transparency.

## ■ Background

Under the federal Anti-Kickback Statute (“AKS”), the federal government may impose criminal and civil penalties on whoever “knowingly and willfully offers, pays, solicits or receives remuneration to induce or reward the referral of business reimbursable under any of the federal health care programs” (e.g., Medicare, Medicaid). Generally, employer-sponsored health plans are not “federal health care programs;” therefore, they are not directly subject to the AKS.

Because the statute had a broad reach, the law was subsequently amended when HHS developed regulations to create “safe harbors.” The safe harbors specify various payment and business practices that, if followed, are not subject to sanctions under the AKS, even though such practices potentially could be capable of inducing payments that could trigger penalties under this law.

## ■ How would this Proposed Rule Impact Employer-Sponsored Plans?

The proposed rule creates a new safe harbor under the federal AKS related to PBM service fees.

If followed, the safe harbor protects the pharmaceutical manufacturer’s payment for certain services that a PBM furnishes to the manufacturer from anti-kickback claims. For this purpose, the term “health plan” includes employer-sponsored group health plans.

Briefly, to qualify for the safe harbor’s protection as proposed:

1. The PBM and pharmaceutical manufacturer must have a **written agreement** that:
  - a. Covers all of the services the PBM provides to the manufacturer in connection with the PBM’s arrangements with health plans for the term of the agreement; and
  - b. Specifies each of the services to be provided by the PBM to the manufacturer and the compensation for such services.

2. Compensation paid to the PBM must:
  - a. Be consistent with fair market value in an arm's-length transaction;
  - b. Be a fixed payment, not based on a percentage of sales; and
  - c. 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, for which payment may be made in whole or in part under Medicare, Medicaid or other federal health care programs.
  
3. The PBM must disclose in writing, at least annually, to each health plan with which it contracts, and to HHS upon request, the services it rendered to each pharmaceutical manufacturer that are related to the PBM's arrangements with that health plan and associated costs for such services.

The proposed rule establishes a clear pathway for the pharmaceutical manufacturer and PBM to follow and reduce their potential exposure to federal anti-kickback claims. If they opt to use the safe harbor, then the employer-sponsored plan will receive more transparency through the new annual reporting obligation (described in (3) above) and may have favorable cost impact in a fixed fee pricing model (as described in (2) above).

However, nothing in the proposed rule requires the manufacturer and PBM to follow the safe harbor. HHS states that certain types of remuneration manufacturers may pay to PBMs either (1) would not implicate the AKS or (2) could be protected under another existing safe harbor. However, according to the proposed rule, following the safe harbor significantly reduces the risk of anti-kickback claims (which have both criminal and civil penalties).

## ■ Employer Action

This is a **proposed rule**. Nothing in here is final and at this point there are no changes affecting health plans that contract with PBMs and any government programs. There is a 60-day comment window and any final (or interim final guidance) will come at a later date and may not reflect what is currently included in the proposed rule. Employers should expect various stakeholders to voice challenges to these rules. We will continue to monitor developments in this area and will keep you posted of relevant updates.

