

PUBLICATION

HHS Proposes Removing Anti-Kickback Safe Harbor Protection for PBM Rebates, Proposes Two New Safe Harbors

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On January 31, the Department of Health and Human Services (HHS) and HHS Office of Inspector General (OIG) issued for public display a proposed regulation that would subject certain pharmaceutical manufacturer rebates paid to pharmacy benefit managers (PBMs) to criminal and civil penalties under the federal Anti-Kickback Statute (AKS). HHS will publish the proposed rule in the Federal Register on February 6.

HHS proposes to prohibit PBM rebates under the Medicare Part D and Medicaid managed care programs by amending the existing safe harbor regulation (42 C.F.R. 1001.952(h)) that protects "discounts" from Anti-Kickback enforcement action, which include criminal and civil penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration to induce or reward the referral of business reimbursable under federal health care programs.

The proposal is part of the Administration's efforts to address escalating drug prices, with HHS's stated goals to reduce both beneficiary out-of-pocket drug costs and federal expenditures under Medicare Part D and Medicaid. HHS also proposes to create a new safe harbor to protect point-of-sale discounts that drug manufacturers provide directly to patients, as well as a second new safe harbor to protect certain administrative fees paid by manufacturers to PBMs.

Actuarial analyses cited by HHS suggest the proposal could reduce beneficiary out-of-pocket costs but could also increase premiums and federal expenditures. The financial impact would vary by beneficiary, with many beneficiaries likely paying more in premiums than they would save in cost sharing.

Proposal to Remove Safe Harbor Protection for PBM Rebates

Under the existing rebate framework for prescription drugs, manufacturers often pay rebates to PBMs in return for favorable formulary placement. Manufacturers typically pay the rebates retrospectively, after initially selling a drug at a wholesale list price that is substantially higher than the net prices, post-rebate. In the preamble to the proposed rule, HHS notes that this rebate framework incentivizes manufacturers to increase list prices and provide larger rebates. Although the system results in lower net prices, beneficiary costs and federal health care program expenditures are often tied to list prices. HHS proposes to eliminate retrospective PBM rebates in the Medicare Part D and Medicaid managed care markets to address these concerns.

To provide PBM rebates consistent with the Anti-Kickback Statute, manufacturers have relied on a statutory safe harbor and HHS regulations that protect "discounts" from Anti-Kickback enforcement action. 42 U.S.C. 1320a-7b(b)(3)(A); 42 C.F.R. 1001.952(h). The proposed rule would update the regulatory discount safe harbor to explicitly exclude from protected discounts a "reduction in price or other remuneration from a manufacturer in connection with the sale or purchase of a prescription pharmaceutical product to a plan sponsor... or to a pharmacy benefit manager acting under contract with a plan sponsor under Medicare Part D, or Medicaid Managed Care Organization, unless it is a price reduction or rebate that is required by law."

HHS, in proposing to update the discount safe harbor regulation, does not specifically comment whether PBM rebates that are not passed on to beneficiaries currently qualify for safe harbor protection. Rather, HHS asserts that it proposes to update the safe harbor regulation "out of an abundance of caution and desire to offer bright line guidance."

The proposal also addresses other existing rebates in the pharmaceutical marketplace. HHS makes clear it does not intend to remove protection from rebates required by law, such as rebates under the Medicaid drug rebate program. HHS also intends for protection to continue for drug discounts offered to entities such as wholesalers, hospitals, physicians, pharmacies, and third-party payors in other federal health care programs. The agency is soliciting comments on whether the proposed amendments to the safe harbor regulation would exclude from protection any price reductions "not contemplated by the proposed amendment."

The effective date of the proposed update to the safe harbor regulation would be January 1, 2020. HHS asks for comments on whether the proposed effective date would provide sufficient time to restructure arrangements that would no longer be protected by the discount safe harbor.

Proposal to Create New Safe Harbor for Point-of-Sale Discounts

In addition to removing safe harbor protection for rebates retained by PBMs, HHS proposes to create a new safe harbor to protect point-of-sale discounts passed on to beneficiaries. The proposed safe harbor would protect from Anti-Kickback enforcement a drug price reduction payable under Medicare Part D or by a Medicaid managed care organization (MCO), so long as the price reduction: (1) is set in advance with a Part D plan sponsor, Medicaid MCO, or PBM; (2) does not involve a rebate, unless the discount is provided to the pharmacy through a chargeback or is required by law; and (3) is applied to the price charged for the drug to the beneficiary at the point of sale.

HHS is soliciting feedback on the extent to which the safe harbor would incentivize manufacturers to provide point-of-sale discounts and whether HHS should modify the proposed safe harbor to encourage such discounts. HHS proposes that the effective date of the new safe harbor would be 60 days after publication of the final rule.

Proposal to Create New Safe Harbor for Service Fees

HHS also proposes to create a new safe harbor to protect certain service fees paid by manufacturers to PBMs. The proposed safe harbor would protect from Anti-Kickback enforcement any payment by a manufacturer to a PBM for services the PBM provides to the manufacturer "related to the pharmacy benefit management services that the PBM furnishes to one or more health plans," so long as: (1) the PBM has a written agreement with the manufacturer that covers and specifies the services and associated compensation; (2) the payment to the PBM is consistent with fair market value in an arm's-length transaction, is a fixed payment, and does not take into account volume or value of referrals or business between the parties; and (3) the PBM discloses in writing to each contracted health plan, and to HHS upon request, the services rendered to manufacturers.

HHS intends for the proposed new safe harbor to protect manufacturer payments to PBMs only for services provided to a manufacturer for the manufacturer's benefit and only when the services relate to the PBM's provision of pharmacy benefit management services to health plans. The safe harbor would only protect services provided to a manufacturer, not to a health plan. HHS provides as an example services provided to manufacturers that "depend on or use data gathered by PBMs from their health plan costumers." In addition, HHS makes clear that the safe harbor would only protect flat fees, not percentage-based fees, as flat fees pose "lower risk of abuse and conflicts of interest."

HHS notes the possibility that certain service fees paid by manufacturers to PBMs may not implicate the AKS or could be protected by existing safe harbors. Nevertheless, HHS proposes the new safe harbor to "provide a

pathway, specific to PBMs, to protect remuneration in the form of flat fee service fees that would be low risk if they meet specified criteria." This is a clear warning shot regarding HHS's apparent view that current percentage-based service arrangements between manufacturers and PBM potentially implicate the AKS.

Implications and Next Steps

The proposed removal of Anti-Kickback safe harbor protection for retrospective rebates paid by drug manufacturers to PBMs, if finalized, would be a significant transformation of the current prescription drug payment system. Indeed, the proposal is a blunt instrument that would effectively criminalize core aspects of the current PBM business model. Importantly, the reach of the proposal would extend only to rebates paid to PBMs in the Medicare Part D and Medicaid managed care markets. In discussion of the proposal since its publication, HHS has asked for Congress to consider enacting legislation to limit use of PBM rebates in the commercial markets.

Stakeholders will have 60 days from publication of the proposed rule in the Federal Register to submit comments to HHS. Baker Donelson will continue to monitor developments related to Anti-Kickback safe harbors and the use of prescription drug rebates. For questions, please contact [Craig Holden](#) or any member of the [Baker Ober Health Law Group](#).