HHS Proposes Anti-Kickback Safe Harbor Revisions that Would Impact Drug Manufacturer Rebates to Health Plans, MCOs, and Pharmacy Benefit Managers

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On January 31, 2019, the Department of Health and Human Services (HHS) Office of the Inspector General (OIG) proposed a new rule that would amend the safe harbor regulations under the Federal anti-kickback statute (42 U.S.C. § 1320a-7b).[1] The anti-kickback statute prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration intended to induce or reward the referral of business reimbursable under a Federal health care program. The safe harbor regulations under the anti-kickback statute provide protection from liability for some payments, including certain discounts, when the safe harbor conditions are met.

Revisions to the Discount Safe Harbor

The discount safe harbor removes from the definition of prohibited remuneration a discount, which is generally defined as a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction, as long as certain conditions are met. The proposed rule would provide some additional limitations on permissible discounts under the safe harbor, excluding from the safe harbor certain rebates or reductions in price or other remuneration on a prescription drug that manufacturers typically offer to plan sponsors under Medicare Part D, Medicaid managed care organizations (MCOs), and pharmacy benefit managers (PBMs).

As reasoning for its proposal, HHS expressed concerns that the current rebate system is not beneficial to health care programs or beneficiaries, nor is it "innocuous," stating "[t]here are significant concerns about the ways in which the current rebate framework may be increasing financial burdens for beneficiaries." Under the current rebate system, rebates do not flow through to consumers, and consumers end up paying an out-of-pocket cost that is more closely related to a drug's list price than to the rebated amount. HHS also noted that rebates are commonly applied to reduce premiums for all enrollees, although, according to a 2011 OIG study, Part D plan sponsors commonly underestimate rebates in their bids. As a result, beneficiaries of the plan may not fully benefit from a premium reduction. In addition, HHS expressed concern that increases in costs for Part D brand name drugs have led to higher beneficiary out-of-pocket costs.

HHS also stated that it believed that the current rebate system has the ability to skew decisions regarding which drugs appear on drug formularies. Rebates create financial incentives to make formulary decisions based on rebate potential and plans may be deterred from placing lower-cost, but therapeutically equivalent drugs, on their formularies or incentivized to give preferred formulary placement to a higher-cost drug that carries a higher associated rebate. HHS also expressed concern that, to the extent the rebate system may fuel high list prices, the system may be increasing costs to Medicare and Medicaid. The proposal would better align the incentives among

1 42 C.F.R. 1001.952(h). "The term discount does not include—(i) cash payment or cash equivalents …; (ii) supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology; (iii) a reduction in price applicable to one payer but not to Medicare, Medicaid or other Federal health care programs; (iv) a routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary; (v) warranties; (vi) services provided in accordance with a personal or management services contract; or (vii) other remuneration, in cash or in kind, not explicitly described in paragraph (h)(5) of this section." 42 C.F.R. § 1001.952(h)(5).

manufacturers and plan sponsors, which, in turn, may help to curb list price increases, reduce consumer financial burden, lower Federal expenditures, improve transparency, and reduce the likelihood that rebates would inappropriately increase business reimbursed by Medicare Part D or Medicaid MCOs.

Addition of New Safe Harbors

The proposed rule would also create two new safe harbors. The first is a point-of-sale reduction in price for prescription pharmaceutical products which would allow manufacturers to provide a reduction in price on a drug if the reduction is applied to the consumer's price at the point of sale. The price is required to be set in advance and must not involve a rebate, unless required by law or the value of the reduction is provided to the dispensing pharmacy through a chargeback.
The second safe harbor is for certain service arrangements between drug manufacturers and PBMs that are set at a fixed price. The safe harbor covers payments drug manufacturers make to PBMs for services provided to the pharmaceutical manufacturer when the services relate to the PBMs' arrangement to provide pharmacy benefit management services.
To qualify for this safe harbor, the agreement must be: (1) set out in writing; (2) cover all of the services provided by the PBM to the manufacturer in connection with the arrangement; and (3) specify each of the services provided and the compensation. Compensation must be consistent with fair market value in an arms-length transaction, be fixed, and not based on the volume or value of referrals.

AGG Observations

- The proposal signifies the Trump administration's continued efforts to combat increasing drug prices and increase transparency in the pharmaceutical industry.
- Pharmaceutical companies should monitor the proposal and be prepared to modify policies to align with any changes.
- If adopted, the new safe harbor may allow for co-payment coupons to Medicare and Medicaid beneficiaries, which is an important sea change.

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