OIG Issues Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons

On September 19, 2014, the Department of Health and Human Services Office of Inspector General ("OIG") issued a Special Advisory Bulletin on Pharmaceutical Manufacturer Coupons (the "Advisory Bulletin")[1] warning pharmaceutical manufacturers that they risk sanctions under the federal anti-kickback statute if they fail to take appropriate steps to ensure their copayment coupons[2] do not induce the purchase of drugs paid for by a federal health care program. The OIG released the Advisory Bulletin in conjunction with a report by the OIG's Office of Evaluation and Inspections, which concluded that the safeguards pharmaceutical manufacturers currently use to prevent their copayment coupons from being used by Medicare Part D ("Part D") beneficiaries may not prevent *all* copayment coupons from being used for drugs paid for by Part D (the "OEI Report").[3]

The OEI Report

The OEI Report voiced concerns that copayment coupons may be used by Part D beneficiaries. Such use may cause Part D beneficiaries to choose more expensive brand-name drugs over generics and therefore impose significant costs on the Part D program. The report assessed the safeguards that pharmaceutical manufacturers employ to prevent use of copayment coupons by Part D beneficiaries. The report identified two primary safeguards: (i) notices to federal health care program beneficiaries and pharmacists that the copayment coupon may not be used to purchase drugs paid for by a federal health care program; and (ii) manufacturers' use of pharmacy claims edits. The report concluded that these safeguards do not adequately prevent use of these coupons by all Part D beneficiaries, for reasons including (i) the prevalence of inconspicuous notices; (ii) manufacturers' lack of access to Part D enrollment status data, and their subsequent reliance on "proxies" to approximate Part D coverage; and (iii) manufacturers' inability to verify accuracy of claims edits because they do not audit the process. Additionally, the report noted that primary insurers, including Part D plans, cannot undertake their own independent review of copayment coupon use by their beneficiaries because the coupons are typically processed as secondary insurance claims. In light of the findings above, the OEI Report recommended that the Centers for Medicare & Medicaid Services ("CMS") cooperate with industry stakeholders to identify potential solutions that will ensure coupons are not used for drugs paid for by Part D, including CMS's facilitating verification of Part D enrollment and improving transparency of pharmacy claims data so Part D plans and other entities can more easily identify when coupons have been applied.

The Advisory Bulletin

The Advisory Bulletin reminds pharmaceutical manufacturers of their obligation to operate their copayment coupon programs in compliance with federal law, including the federal anti-kickback statute. Citing the findings of the OEI Report, the OIG specifies that a manufacturer's failure to take appropriate steps to ensure its copayment coupons do not induce the purchase of federal health care items or services may be evidence of intent to induce the purchase of drugs paid for by federal health care programs, in violation of the anti-kickback statute. The OIG also notes that while the Advisory Bulletin and OEI Report focus on

[1] Advisory Bulletin available here.
[2] For purposes of the Advisory Bulletin, copayment coupons are defined as "any form of direct support offered by manufacturers to insured patients to reduce or eliminate immediate out of pocket costs for specific prescription medications. They include print coupons, electronic coupons, debit cards, and direct reimbursements."
[3] OEI Report available here.

pharmaceutical manufacturers, pharmacies that accept these coupons from federal health care beneficiaries may also be subject to sanctions under the anti-kickback statute, the beneficiary inducement provisions of the civil monetary penalties law and the False Claims Act. While the OIG acknowledged in the Advisory Bulletin that copayment coupons may encourage beneficiary adherence to medication regimens (particularly in cases of high copayment obligations), those benefits did not appear to outweigh its concerns, and the OIG reminded manufacturers that the manufacturers can donate to independent charities that provide financial support to patients without regard for the patient's specific medication requirements.

The Advisory Bulletin is cause for pharmaceutical manufacturers and pharmacies to review their own practices and existing safeguard mechanisms to ensure copayment coupons are not used in connection with federal health care programs. Based on the OEI Report findings, all manufacturers, as a general matter, should ensure their notices are clear and conspicuous. Any other identified weaknesses or vulnerabilities should also be addressed in order to avoid potential claims of improper inducement. For example, those manufacturers that employ eligibility questionnaires to prevent federal health care program beneficiaries from accessing copayment coupons can consider implementing secondary safeguards, such as a tracking mechanism, to prevent beneficiaries from changing their answers in order to obtain the coupon. The OIG, however, acknowledges that complete transparency and effective limits on the use of copayment coupons may require an industry-wide effort involving manufacturers, Part D plans and CMS. This acknowledgment calls into question the extent to which manufacturers alone can ensure their coupon programs are not used for drugs paid for by a federal health care program.

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Should you have questions regarding this alert, please contact your usual Ropes & Gray advisor.