DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

Special Advisory Bulletin

Pharmaceutical Manufacturer Copayment Coupons

September 2014

Pharmaceutical manufacturers offer copayment coupons to insured patients to reduce or eliminate the cost of their out-of-pocket copayments for specific brand-name drugs.[1] These coupons constitute remuneration offered to consumers to induce the purchase of specific items.

When the item in question is one for which payment may be made, in whole or in part, under a Federal health care program (including Medicare Part D), the anti-kickback statute is implicated. The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program. Section 1128B(b) of the Social Security Act (the Act).[2] Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated.

A claim that includes items or services resulting from a violation of the anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Section 1128B(g) of the Act.[3] The False Claims Act imposes liability for knowingly presenting or causing to be presented a false claim for payment by the United States. 31 U.S.C. § 3729.[4]

[1] For purposes of this Special Advisory Bulletin, copayment coupons are 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, as described in OIG report entitled, *Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs*, OEI-05-12-00540 (OEI Report).

[2] 42 U.S.C § 1320a-7b(b). "Federal health care program" is defined at section 1128B(f) of the Act and includes programs such as Medicare and Medicaid. 42 U.S.C. § 1320a-7b(f).

[3] 42 U.S.C. § 1320a-7b(g).

[4] In addition, section 1128A(a)(5) of the Act provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is

Cost-sharing requirements for Federal health care program drugs serve an important role in protecting both Federal health care programs and their beneficiaries. These cost-sharing requirements promote: (1) prudent prescribing and purchasing choices by physicians and patients based on the true costs of drugs and (2) price competition in the pharmaceutical market. While copayment coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries.[5] The availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices. Excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent.

The pharmaceutical industry is aware of the anti-kickback statute and its application to copayment coupons. Copayment coupons typically bear a statement that the coupon may not be used by beneficiaries of Federal health care programs.

The Office of Inspector General, Office of Evaluation and Inspections (OEI), conducted a study analyzing the measures pharmaceutical manufacturers use to prevent their coupon programs from inducing the purchase of drugs paid for by Part D. We are issuing this Special Advisory Bulletin concurrently with the OEI Report.[6]

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likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid) (the beneficiary inducement CMP). 42 U.S.C. § 1320a-7a(a)(5). In circumstances in which the offer or acceptance of copayment coupons may induce a beneficiary to use a particular practitioner or pharmacy, a violation of this statute may occur.

[5] We recognize that copayment support may benefit beneficiaries by encouraging adherence to medication regimens, particularly when copayments are so high as to be unaffordable to many patients. Manufacturers that desire to assist Federal health care program beneficiaries who cannot afford their copayments have the option of donating to independent charities that provide financial support to patients without regard for the particular medication a patient may be using. For guidance specifically related to such charities, see OIG Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 26, 2014) available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf and OIG Special Advisory Bulletin on Patient Assistance Programs of Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf .

[6] Like the OEI report, this Special Advisory Bulletin focuses on the measures used by pharmaceutical manufacturers in connection with the copayment coupons they offer. However, pharmacies that accept manufacturer coupons for copayments owed by Federal health care program beneficiaries also may be subject to sanctions under the anti-kickback statute, the beneficiary inducement CMP, and the False Claims Act.

The OEI Report describes measures that surveyed manufacturers report they have in place to prevent use of copayment coupons to fund copayments for drugs paid for by Part D and concludes that these measures may not prevent all such use. It states that all manufacturers place notices on the coupons or coupon materials that Federal program beneficiaries are not eligible to use them, for at least some coupon formats. However, not all manufacturers use such notices on all coupon formats. In addition, while most manufacturers also use claims edits in the processing of at least some of their coupons, the OEI Report concludes that these claims edits may not reliably identify all claims submitted in connection with drugs paid for by Part D. The OEI Report also finds that coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers, which impedes Part D plans and others from identifying and monitoring the use of coupons for drugs paid for by Part D. The OEI Report recommends that the Centers for Medicare & Medicaid Services (CMS) cooperate with industry stakeholder efforts to improve the reliability of mechanisms to determine when copayment coupons are used in connection with the purchase of drugs paid for, in part, by Part D. These mechanisms include improving the reliability of claims edits and making copayment coupons universally identifiable in pharmacy claims transactions. Such transparency with respect to coupon use would permit all Federal health care program payors—not just the sponsors of Part D plans—to recognize coupon transactions.

Regardless of future actions by CMS, the offerors of coupons ultimately bear the responsibility to operate these programs in compliance with Federal law. Pharmaceutical manufacturers that offer copayment coupons may be subject to sanctions if they fail to take appropriate steps to ensure that such coupons do not induce the purchase of Federal health care program items or services, including, but not limited to, drugs paid for by Medicare Part D. Failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the anti-kickback statute.