On September 19, 2014, the U.S. Department of Health and Human Services Office of Inspector General (“OIG”) released a study showing that pharmaceutical manufacturer safeguards to prevent Medicare Part D (“Part D”) beneficiaries from using co-pay coupons may not be completely effective. The study analyzed 40 co-pay coupons from 30 pharmaceutical companies, along with the disclaimers included with the coupons and the pharmacy claims edits used to identify and disqualify Part D enrollees. The study found that these safeguards have had only limited effectiveness because (1) written disclaimers and warnings cannot stop a patient from presenting a coupon at a pharmacy, and (2) while claims edits can prevent a discount from being applied, most manufacturers use inaccurate information to identify Part D enrollees.

Simultaneously with the issuance of the report, OIG issued a Special Advisory Bulletin stating that manufacturers are responsible for ensuring that their co-pay coupon programs do not induce federal health benefit beneficiaries to purchase their branded drugs over generics. Therefore, pharmaceutical manufacturers must take note that the identified deficiencies in Part D enrollment verification could result in criminal and civil liabilities.

enforcement actions under the Federal anti-kickback statute ("AKS")\(^3\) and the False Claims Act ("FCA").\(^4\)

While the Special Advisory Bulletin and report suggest heightened scrutiny of manufacturer coupons made available to Part D beneficiaries, the OIG has proposed new rules published on October 3, 2014, that would provide safe harbor protection and CMP exceptions for certain items and services to Part D beneficiaries that meet specified requirements.\(^5\) The proposed rule will be discussed in a separate EBG Client Alert that will soon be available.

**Federal Fraud and Abuse Laws**

The AKS prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration to induce the purchase of any item or service for which payment may be made in whole or in part under a federal health care program. As a result of changes made to the Social Security Act as part of the Patient Protection and Affordable Care Act, if any action that violates the AKS results in claims for reimbursement from a federal health care program, the government may also seek civil damages under the FCA.\(^6\)

Pharmaceutical manufacturers may be liable under the AKS and the FCA if they offer coupons to induce patients to choose, or physicians to prescribe, more expensive branded drugs over lower cost generics. The beneficiary inducement civil monetary penalties ("CMPS") may be implicated if the coupons induce patients to choose a particular provider, practitioner, or supplier. The OIG expressed the concern that even though the manufacturer pays all or a portion of the higher co-pay associated with the branded drug, the federal health care program must cover the remainder of the significantly higher cost.

**OIG Report Findings**

Pharmaceutical manufacturers typically employ two types of measures to prevent federal health program beneficiaries from using co-pay coupons for branded drugs: (1) written notices to beneficiaries and pharmacists and (2) claims edits to check the enrollment status of the patient attempting to use the coupon. OIG found that beneficiary and pharmacist notices are generally ineffective because they are printed in small fonts or are displayed separate from the coupon itself. Also, OIG found that notices to pharmacists have little effect because many alerts appear throughout pharmacy claims transactions, and pharmacists may pay little attention to additional alerts. Moreover, both forms of notice merely provide warning about eligibility and

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\(^3\) 42 U.S.C. § 1320a-7b(b) (2012).

\(^4\) Id. § 1320a-7b(g).


cannot actually prevent a Part D beneficiary from presenting a co-pay coupon at a pharmacy.

The OIG noted that pharmacy claims edits provide a more effective method of preventing Part D beneficiaries from using co-pay coupons because the manufacturer rebate program uses provider- or patient-specific information to verify the patient’s enrollment status. However, OIG found that most manufacturers use payer bank identification numbers (“BINs”) or the patient’s date of birth (i.e., the patient’s age) to determine Part D enrollment status, both of which are unreliable reference points. A payer’s BIN cannot always identify Part D coverage because manufacturers only collect payer BINs indirectly, and such information may be outdated or inaccurate when it is used in a claims edit. Likewise, a patient’s birthday may not correctly predict Part D coverage because some Medicare beneficiaries are disabled and under the age of sixty-five.

Although processor control numbers and Part D benefit stage information (i.e., patient-specific out-of-pocket spending amounts) could more accurately predict Part D enrollment, most manufacturers have limited or no access to this information. Even using multiple points of information in a pharmacy claims edit could significantly increase the reliability of the edits. However, 30 percent of manufacturers reported that their claims edits only check the primary insurer’s BIN. Another 20 percent of manufacturers’ claims edits rely on Part D benefit stage information, and 17 percent rely on the patient’s date of birth.

OIG found two other circumstances that prevent the coupon system from operating efficiently. First, the majority of manufacturers do not audit their claims edit process through process reviews or retrospective claims reviews and therefore cannot verify whether the edits are applied correctly. Second, Part D plans cannot provide a supplemental layer of review because application of a co-pay coupon at a pharmacy is treated as a secondary insurance claim that occurs after the primary insurance claim has been processed.

**Considerations for Manufacturers and Pharmacies**

OIG sends a clear message through the report and the advisory bulletin that a manufacturer will be liable for any inducement of physicians to prescribe the manufacturer’s brand name drug over a generic under the AKS and for any resulting sales subject to the FCA stemming from a co-pay coupon program if adequate protections to identify and exclude Part D beneficiaries are not in place. OIG states that failure to establish such protections supplies evidence of intent necessary to prove AKS claims. In addition, although the OIG focused on the liability of manufacturers, the Special Advisory Bulletin states in a footnote that pharmacies accepting manufacturer coupons for Part D beneficiaries may also be sanctioned under the AKS, FCA, and the beneficiary inducement CMPs.

In light of the Special Advisory Bulletin and report, manufacturers should ensure that:
• co-pay coupon programs for all products use pharmacy claims edits that use reliable, accurate insurer or beneficiary information;
• pharmacy claims edits check multiple points of insurer and beneficiary information;
• prominent, easy-to-read warnings about federal health care program exceptions are affixed to coupons, debit cards, and other means of providing rebates; and
• audits of pharmacy claims edits are conducted regularly to ensure accuracy.

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This Client Alert was authored by Constance Wilkinson, Alan Arville, and Benjamin Zegarelli. For additional information about the issues discussed in this Client Alert, please contact one of the authors or the Epstein Becker Green attorney who regularly handles your legal matters.

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