

# PUBLICATION

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## OIG Warns About Risk of Drug Coupons, But Offers No Solution [Ober|Kaler]

September 25, 2014

On September 18, 2014, the OIG simultaneously issued a [Report](#) and [Special Advisory Bulletin](#) warning about the potential fraud and abuse risks posed by coupons offered by pharmaceutical manufacturers when those coupons are used by federal health care program beneficiaries. The two documents should be read in tandem. The Report describes current industry efforts to prevent the use of coupons by federal health care program beneficiaries and the inherent limitations of those efforts. For its part, the Special Advisory Bulletin describes the fraud and abuse risk to pharmaceutical manufacturers (as well as pharmacies) and warns that failure to take “appropriate steps” could be evidence of intent to violate the law. In the end, however, the OIG fails to say what those appropriate steps should be. The OIG simply calls on CMS to work with pharmaceutical manufacturers and other stakeholders to develop better ways to prevent coupon use by federal health care program beneficiaries.

### Report

The [OIG Work Plan](#) [PDF] has indicated that a study by the Office of Evaluation and Inspection (OEI) of efforts by pharmaceutical manufacturers to prevent coupon use by federal health care program beneficiaries has been under way for more than a year. The ultimate conclusion of the OEI Report is that current safeguards may not prevent all copayment coupons from being used for drugs paid for by Part D.

As part of the study, OEI conducted a survey of 30 pharmaceutical manufacturers of the top 100 Part D brand-name drugs with coupons and with the highest Medicare expenditures. The online survey asked a number of questions about the use of various types of coupons – print coupons, electronic coupons, debit cards, and direct reimbursement – as well as efforts by pharmaceutical manufacturers to prevent the use of any of these types of coupons by federal health care program beneficiaries. The study also involved interviews of staff at various organizations involved in pharmacy claims transactions, including pharmacists, coupon vendors, a switching company, and the National Council for Prescription Drug Programs (NCPDP).

Citing studies from 2011 and 2012, the OIG observed that 6–7 percent of seniors reported using manufacturer coupons toward copayments for prescription drugs purchased through Part D plans. The OIG noted that 36 million people have Part D coverage, so coupon use for drugs covered by Part D could exceed 2 million beneficiaries.

The OIG described the importance of Part D formularies, generic substitution programs, and patient copayments. Together, these approaches are designed to control drug costs for Part D plans. The OIG explained that coupon programs may be offered by pharmaceutical manufacturers for several reasons. First, coupons may help retain market share when other drugs are available to treat a condition. Second coupon programs may be a way to encourage patients to adhere to their prescription drug regimens. Third, pharmaceutical manufacturers may use coupons to offset the high cost of some specialty and biologic drugs.

Based on its study, the OIG found that current safeguards by pharmaceutical manufacturers “may” not prevent all coupons from being used for drugs paid for by Part D. The OIG found that all of the surveyed manufacturers used some type of notice directed at beneficiaries and pharmacists. There were variations in the types of notices used and, in fact, notices were not used in conjunction with all coupons. The OIG also found that most

manufacturers use some type of pharmacy claims edits. A variety of different edits were used, with each having limitations.

- Edits that rely on the primary insurer's BIN are not effective. Insurers would need an up-to-date list of insurers that have federal health care programs plans that includes both the BIN and the PCN.
- Some edits look for Part D Benefit Stage information, because there will only be data if a patient has Part D coverage.
- Other edits use the patient's date of birth. However, OIG points out that 17 percent of Medicare beneficiaries are disabled and under age 65.

Finally, the OIG examined the ability of Part D plans and other entities to identify pharmaceutical manufacturer coupons on pharmacy claims. Coupons are typically processed as secondary insurance claims after the Part D plan has processed the primary insurance claim. There is nothing else to indicate that a coupon has been utilized. Thus, Part D plans have no real ability to identify when coupons are used.

The OIG concluded its Report by reiterating the potential risk under the antikickback statute when coupons are used by beneficiaries of federal health care programs. The OIG recommended to CMS that it cooperate with various stakeholders in developing a long-term solution to preventing such usage.

## Special Advisory Bulletin

In the Special Advisory Bulletin, the OIG outlined the potential liability of pharmaceutical manufacturers from coupons used by federal health care program beneficiaries. The OIG focused on False Claims Act liability based on a violation of the antikickback statute. The OIG also warned of risks under the civil monetary penalty (CMP) provision against inducements to beneficiaries. In a footnote, the OIG also pointed out that pharmacies that accept coupons from pharmaceutical manufacturers may be subject to sanctions under the antikickback statute, the beneficiary inducement CMP, and the False Claims Act.

The OIG briefly described the findings of the Report and stressed that existing measures “may” not prevent all use of coupons by federal health care program beneficiaries. The OIG recognized the limitations of existing efforts.

Despite these limitations, the OIG warned that the offeror of coupons ultimately bears the responsibility to operate its coupon programs in compliance with federal law. The OIG added that pharmaceutical manufacturers that fail to take appropriate steps to avoid inappropriate use of their coupons could be found in violation of the anti-kickback statute. In an odd twist for a Special Advisory Bulletin, however, the OIG failed to say what those appropriate steps should be. Instead, the OIG recommended that CMS work with pharmaceutical manufacturers and other stakeholders to develop better ways to prevent coupon use by federal health care program beneficiaries.

## Ober|Kaler Comments

In an unusual move, the OIG laid out the threat but failed to propose a solution. The OIG simply states that pharmaceutical manufacturers that offer coupons must take appropriate steps to ensure coupons are not used by federal health care program beneficiaries. This unusual approach is due to the fact that, under the current system, there is no effective way for manufacturers, Part D plans, or even OIG or CMS to identify and prevent all coupons from being used by federal health care program beneficiaries.

In light of the findings in the Report regarding the various approaches taken by pharmaceutical manufacturers, pharmaceutical manufacturers will be under greater pressure to consistently use safeguards and perhaps establish industry standards. We would also expect pharmaceutical manufacturers and their industry associations to work with CMS and Part D plans to develop ways to make electronic edits more effective, perhaps by establishing a comprehensive BIN/PCN list of Part D plans that manufacturers can use as part of an edit process. Eventually, the NCPDP standards may be changed to protect against the use of coupons by federal health care beneficiaries. The OIG, however, recognizes in the Report that NCPDP changes “typically take years to complete.”