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OIG WARNS THAT MANUFACTURER SAFEGUARDS MAY NOT PREVENT COPAYMENT COUPON USE FOR PART D DRUGS

OVERVIEW

The Department of Health & Human Services Office of Inspector General ("OIG") recently released a Special Advisory Bulletin on the fraud and abuse implications of pharmaceutical manufacturers offering copayment coupons to reduce or eliminate the cost of out-of-pocket copayments for brand-name drugs. The Special Advisory Bulletin and the concurrent OIG Office of Evaluations and Inspections report ("OEI Report") focus specifically on implications when those coupons are used by federal health care program beneficiaries, including individuals covered by Medicare Part D. The Special Advisory Bulletin and OEI Report outline current safeguards used by pharmaceutical manufacturers to prevent copayment coupon use for Part D drugs and conclude that existing manufacturer safeguards may not adequately prevent coupons from being used for drugs covered by Part D.

ANALYSIS

OEI Report. The Anti-Kickback Statute prohibits the knowing and willful offer or payment of remuneration to a person to induce the purchase of any item or service for which payment may be made by a federal health care program. Pharmaceutical manufacturers may be liable under the Anti-Kickback Statute if they offer coupons to induce the purchase of drugs paid for by any federal health care program, including but not limited to Medicare Part D.

According to recent surveys, approximately 6-7% of seniors report using manufacturer coupons toward their copayments for Part D drugs. Although coupons are sometimes offered by manufacturers to encourage patients to comply with their medication regimen, one concern with coupons is that they may encourage Medicare beneficiaries to select more expensive brand-name drugs over lower cost alternatives, thus increasing costs to Part D.

In order to identify and analyze the safeguards used by pharmaceutical manufacturers to prevent copayment coupons from being used to purchase drugs paid for by Part D, the OIG's Office of Evaluations and Inspections ("OEI") surveyed 30 manufacturers of the top 100 Part D brand-name drugs with coupons and the highest Medicare expenditures, reviewed safeguards offered for those drugs and interviewed staff at organizations involved in pharmacy claims transactions to identify vulnerabilities associated with coupon use.

The OEI Report concluded that current manufacturer safeguards may not prevent all copayment coupons from being used for drugs paid for by Part D. Specifically, the OEI Report found the following:

- To reduce potential risk under the Anti-Kickback Statute, all manufacturers surveyed for the OEI Report claimed to provide notices to Medicare beneficiaries and pharmacists, stating that coupons may not be used to purchase drugs paid for by federal health care programs. The format of such notices varied widely, although the OEI Report found that most notices were printed in small font. Additionally, not all manufacturers used notices on all coupon formats (print, electronic, debit cards and direct reimbursement). OEI concluded that because such notices only communicated information about the terms and conditions of the coupons, the notices could not entirely prevent coupons from being used to purchase Part D drugs.
- Most manufacturers reported using pharmacy claims edits to prevent coupons from being processed for Medicare beneficiaries. However, OEI found that many of these edits do not prevent coupons from being processed because manufacturers cannot access a beneficiary's actual Medicare enrollment status. Manufacturers' claims processing edits use proxies that cannot replicate actual enrollment information and use data that may be unreliable.
- OEI noted that entities such as Part D plans, other primary insurers and pharmacies have difficulty identifying coupons as they are processed or after they are adjudicated due to limitations with pharmacy claims transaction systems. This impedes the ability of such entities to prevent coupon use for Part D drugs and also makes it difficult for CMS and OIG to monitor coupon use.

As the agency responsible for administration of the Part D program, OEI recommends that CMS cooperate with industry efforts to identify solutions to prevent coupon use for Part D drugs. Specifically, OEI suggests that CMS could explore how to make coupons identifiable and transparent in pharmacy claim transactions and recommends that CMS work with the industry to facilitate confirmation of patients' Medicare insurance status.

The full OEI Report can be found here. OEI also released a short podcast from Melissa Baker, an OEI team leader in Chicago, that discusses the above findings of the OEI Report. A transcript of the podcast is available here.

Special Advisory Bulletin. The Special Advisory Bulletin, released concurrently with the OEI Report, summarizes the OEI Report and cautions that pharmaceutical manufacturers offering copayment coupons may be subject to sanctions if they do not take appropriate steps to ensure that such coupons do not induce the purchase of drugs paid for by Part D. The Special Advisory Bulletin further clarifies that regardless of any future action by CMS, entities that offer copayment coupons bear ultimate responsibility for operating coupon programs in compliance with federal law.

PRACTICAL TAKEAWAYS

Pharmaceutical manufacturers and pharmacies should review their practices to ensure that they have appropriate mechanisms in place to prevent patient use of coupons for drugs paid for by federal health care programs. In addition to analyzing their current safeguards for effectiveness, manufacturers and pharmacies are encouraged to engage industry stakeholders and CMS in an effort to identify a practical solution. CMS has stated that it is willing to cooperate with industry efforts to improve safeguards to ensure the proper use of copayment coupons.

If you have any questions or would like additional information about this topic, please contact Julie K. Lappas at (317) 977-1490 or jlappas@hallrender.com or your regular Hall Render attorney.

Special thanks to Grace Shelton, law clerk, for her assistance with the preparation of this Health Law News article.

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