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OIG Special Advisory Bulletin Provides Guidance on Application of Federal Anti-Kickback Statute to Pharmaceutical Manufacturer Copayment Coupons



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In recent years, copayment coupon programs have become standard promotional practices for both large and small pharmaceutical manufacturers. Copayment coupons are typically offered to commercially insured patients in order to reduce or eliminate out-of-pocket costs for specific brand name drugs with higher copays.

Since their inception, prescription drug copayment coupon programs have been a source of controversy—favored by brand manufacturers, physicians, and patients, and opposed by generic manufacturers, health insurers, third party payers, and pharmaceutical benefit managers (PBMs).

Health plans and PBMs have strongly criticized copayment coupon programs, arguing that such programs undermine their cost-sharing and formulary benefit design structures intended to control drug costs. They also cite to studies concluding that many copayment coupons are offered on brand-name medications for which generic alternatives are available.[1] Opponents of copayment coupons also argue that coupons increase costs not only for health plans but also for patients, as coupons are nearly always time-limited and the short-term savings do not typically outweigh the long-term cost of taking a brand name drug.[2] On the other hand, proponents of copayment coupon programs argue that reducing copayments improves medication adherence and clinical outcomes and, therefore, is an effective means to reducing total health care spending.[3]

The copayment coupon controversy has carried over into the courts. On March 7, 2012, multiple health plans filed seven lawsuits in federal district courts against a number of pharmaceutical manufacturers alleging that the manufacturers' copayment coupon programs violate antitrust, commercial bribery, and racketeering laws. Although several of the lawsuits have since been dismissed, these lawsuits highlight the intense debate generated by copayment coupon programs.

Adding to the debate, the Secretary of the U.S. Department of Health and Human Services (HHS) made headlines last year when she announced that "[qualified health plans], other programs related to the Federally-facilitated Marketplace, and other programs under Title I of the Affordable Care Act" are not "fed-

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[1] Joseph S. Ross, M.D., et al, *Prescription-Drug Coupons—No Such Thing as a Free Lunch,* New England Journal of Medicine (Sep. 25, 2013), *available at* http://www3.med.unipmn.it/papers/2013/NEJM/2013-09-26_nejm/nejmp1301993.pdf.

[2] *Id.*

[3] Leah L Zullig, PhD, MPH, et al., *Ingredients of Successful Interventions to Improve Medication Adherence,* JAMA (Dec. 25, 2013), *available at* http://jama.jamanetwork.com/article.aspx?articleID=1784085.

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eral health care programs under section 1128B of the Social Security Act''[4] and thus not subject to the federal Anti-Kickback Statute.[5] Many interpreted this announcement as permitting the offer of copayment coupons to individuals insured under the Affordable Care Act Exchanges.

Coupon programs also have increasingly garnered the attention of the HHS Office of Inspector General (OIG). Although manufacturers expressly exclude federal health care program beneficiaries from copayment coupon programs due to federal Anti-Kickback Statute risks, in recent years the OIG has become concerned that such exclusions are routinely ignored. In both its 2013 and 2014 Work Plan, the OIG indicated that it would be reviewing safeguards that pharmaceutical manufacturers have in place to ensure that beneficiaries do not use copayment coupons to obtain prescription drugs paid for by Medicare Part D.[6] In doing so, the OIG pointed to a survey suggesting that beneficiaries are using copayment coupons to obtain specific brand-name prescription drugs, causing Medicare to pay more than necessary when less costly versions of the same drugs are available.[7]

OIG Special Advisory Bulletin Directly Addresses Copayment Coupon Programs

Last month, the OIG followed through on its promise in the 2013 and 2104 Work Plans and released a Special Advisory Bulletin directly addressing pharmaceutical manufacturer copayment coupons.[8] In conjunction with the Special Advisory Bulletin, the OIG's Office of Evaluation and Inspections (OEI) released a Report analyzing the measures utilized by drug manufacturers to prevent the use of copayment coupons by Medicare Part D beneficiaries.[9] The Bulletin and its companion Report advise manufacturers that they risk sanctions if appropriate steps are not taken to ensure that copayment coupons are not inducing the purchase of items or services paid for by federal health care programs.[10]

In the Special Advisory Bulletin, the OIG broadly defines ''copayment coupons'' as any form of direct support offered by manufacturers to insured patients, including print coupons, electronic coupons, debit cards, and direct reimbursements.[11] The OIG also explicitly confirms the longstanding belief that copayment coupons constitute remuneration offered to consumers to induce the purchase of specific prescription drugs and thus implicate the Anti-Kickback Statute.[12] Additionally, the OIG notes that if the copayment coupon induces a beneficiary to use a particular practitioner or pharmacy, the beneficiary inducement civil monetary penalties law (CMP) may also be implicated.[13]

The OEI's study sought to determine the effectiveness of purported safeguards implemented by pharmaceutical manufacturers to prevent the use of copayment coupons by Medicare Part D beneficiaries.

The OEI surveyed 30 pharmaceutical manufacturers who sponsor copayment coupon programs and manufacture drugs that are on the Medicare Part D formulary. They also reviewed current safeguards manufacturers have in place to prevent coupons from being used for drugs paid for by Medicare Part D and interviewed staff involved in pharmacy claims transactions to determine whether appropriate mechanisms were in place to readily identify Medicare Part D claims.

The study revealed that current safeguards may not prevent all copayment coupons from being used for Medicare Part D drugs. Specifically, the OEI study noted the following shortcomings:

- While all surveyed manufacturers place notices on the coupon or coupon materials stating that federal health care program beneficiaries are not eligible to use the copayment coupons, not all manufacturers place these notices on all coupon formats.

- Even though most surveyed manufacturers also use claims edits in the processing of at least some coupons, claims edits did not reliably identify all claims submitted in connection with drugs paid for by Medicare Part D.

- Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers. This lack of transparency impedes Medicare Part D plans and others from identifying and monitoring the use of coupons for drugs paid for by Medicare Part D.

Strengthening the Compliance of Copayment Coupon Programs

In its Special Advisory Bulletin, the OIG concluded that manufacturers risk sanctions under the Anti-Kickback Statute if they fail to take appropriate steps to prevent use of copayment coupons by federal health care program beneficiaries. The OEI Report, through its survey findings, identifies areas of weakness in the copayment coupon process. Manufacturers, Medicare Part D plans, and pharmacies may wish to take a closer look at these areas to identify opportunities to strengthen coupon use protections and address the OIG's Anti-Kickback Statute concerns.

- Clearly state on every form of copayment coupon and all related coupon materials that the coupon cannot be used for drugs reimbursed, in whole or in part, by

[4] U.S. Dept. of Health and Human Services, Letter to U.S. Rep. Jim McDermott (D-Wash.) (Oct. 30, 2013), *available at* http://mcdermott.house.gov/images/The%20Honorable%20Jim%20McDermott.pdf.

[5] 42 U.S.C. § 1320a-7b(b).

[6] U.S. Dept. of Health and Human Services, Office of Inspector General, FY 2014 Work Plan, *available at* http://oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf; U.S. Dept. of Health and Human Services, Office of Inspector General, FY 2013 Work Plan, *available at* https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf.

[7] *Id.*

[8] OIG Special Advisory Bulletin, Pharmaceutical Manufacturer Copayment Coupons (Sep. 2014), *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf. Hereinafter ''OIG Bulletin.''

[9] OIG Office of Evaluation and Inspections, Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs (Sep. 2014), *available at* http://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf. Hereinafter ''OEI Report.''

[10] OIG Bulletin; OEI Report.

[11] OIG Bulletin.

[12] *Id.*

[13] *Id.*

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federal health care programs. The OEI Report specifically points out that federal health care program exclusions are typically written in extremely small font and may not be included in coupon materials other than the coupon card itself.

■ Implement website safeguards that would prevent federal health care program beneficiaries from accessing online copayment coupons. The OEI Reports that very few manufacturer websites include a tracking mechanism to prevent federal beneficiaries from manipulating eligibility questions in order to obtain coupons.

■ Implement, or modify, claims edits systems used to process coupons to ensure that the claims edits system reliably identifies and rejects the use of coupons on all claims submitted in connection with drugs paid for by Medicare Part D. The OEI Report acknowledges that inappropriate coupon use cannot be addressed unless manufacturers are able to accurately identify a Medicare Part D beneficiary's enrollment status.

■ Implement or strengthen existing audits of claims processing edits intended to prevent the inappropriate use of copayment coupons.

■ Develop processes that allow coupon use to be more transparent within the pharmacy claims transaction system so that PBMs, health plans, and pharmacies can identify and more effectively monitor the use of coupons.

Addressing these areas of weakness, the OIG acknowledges, will likely require the coordination and cooperation of multiple stakeholders within the pharmacy claims transaction process, including manufacturers, health plans, PBMs, pharmacies, and CMS.

Alternatives to Copayment Coupon Programs

Because of the increased scrutiny of copayment coupon programs by the OIG and the continued controversy surrounding coupons in general, manufacturers are increasingly considering alternatives to the use of coupons. One month prior to its issuance of the Special Advisory Bulletin and companion Report, the OIG posted an Advisory Opinion approving a pharmaceutical manufacturer's direct-to-patient product sales program.[14]

Under this program, the manufacturer sells brand name drugs for which there is a generic equivalent at a discount to any patient (uninsured, commercially insured, or insured by a federal health care program) who has a valid prescription for the drug. The patient pays for the drug out-of-pocket and no insurer is charged for the cost of the drug. The OIG concluded that although the arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute, the arrangement presented a minimal risk of fraud and abuse.

The OIG's primary rationale for approving the direct-to-patient program was that no health insurers—commercial or government—would be billed for the drug and thus there is no risk of increased costs to federal health care programs. Additionally, the direct-to-patient discount program contained safeguards such as no marketing of federally reimbursable drugs, the prescription drugs were not included on most plan formularies because of the availability of generic equivalents, and there was no inducement for prescribers to switch patients to the higher priced drug.

This favorable Advisory Opinion allows pharmaceutical manufacturers the opportunity to explore direct-to-patient discount programs as an alternative to controversial copayment coupon programs.

Conclusion

Even though the OIG's Special Advisory Bulletin is directed toward pharmaceutical manufacturers, it is important to note that the advisory applies to any entity offering a copayment coupon, as well as pharmacies that accept such manufacturer coupons. Therefore, manufacturers, health plans, PBMs, and pharmacies should all consider reviewing their existing coupon programs and practices in light of the OIG's guidance.

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[14] OIG Adv. Op. No. 14-05 (July 28, 2014), *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/2014/AdvOpn14-05.pdf.