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OIG ISSUES FAVORABLE ADVISORY OPINION ON PRESCRIPTION DRUG DISCOUNT PROGRAM

The Department of Health and Human Services Office of Inspector General ("OIG") recently issued a favorable Advisory Opinion, No. 16-07, of an arrangement that offers Medicare Part D beneficiaries discounts on prescriptions for an erectile dysfunction drug that is statutorily excluded from coverage under Part D (the "Arrangement"). While OIG concluded that the Arrangement could potentially generate prohibited remuneration under the federal Anti-Kickback Statute if the requisite intent to induce or reward referrals were present, OIG stated that it would not impose administrative sanctions because the Arrangement contains a variety of safeguards to reduce the risk of fraud and abuse. Specifically, OIG viewed the fact that the Arrangement operates entirely outside of the Medicare Part D program as the most important safeguard to reducing fraud and abuse risk.

BACKGROUND

The requestor of the Advisory Opinion ("Requestor") markets and distributes a prescription drug (the "Drug") for the treatment of erectile dysfunction. While the Drug is statutorily excluded from coverage under Medicare Part D,[1] it is covered by many private insurance plans and is also available under some federal health care programs, including state Medicaid programs and TRICARE.

Under the Arrangement, Requestor allows individuals who have prescription drug coverage through Medicare Part D ("Part D Beneficiaries") to use a savings card issued by Requestor (the "Card") to receive discounts when filling Drug prescriptions at a pharmacy.[2] The Card, which functions as a coupon, gives Part D Beneficiaries discounts on their out-of-pocket costs greater than $15 up to a maximum benefit of $75 per prescription, for up to 12 Drug prescriptions. Individuals filling prescriptions for the Drug that are paid for by federal or state health care programs other than Part D are not eligible to participate in the Arrangement.

ARRANGEMENT SAFEGUARDS

To activate the Card, individuals must answer several questions to determine if they are eligible to participate in the Arrangement. Eligible individuals must agree not to submit claims for the Drug to their Medicare Part D plan and are informed, upon Card activation, that any out-of-pocket expenses incurred using the Card cannot be applied towards Medicare Part D true out-of-pocket expenses. Additional safeguards include activation of the Card online or via telephone before it can be used and the utilization of real time data by Requestor's contracted vendor to detect attempted Card use by individuals who are ineligible to participate in the Arrangement.

While prescriptions for the Drug may be filled at any pharmacy, Requestor provides pharmacies with detailed written instructions for processing Drug claims for patients with different types of insurance coverage. Specifically, Requestor directs pharmacies to process Part D Beneficiaries as cash-paying customers when filling Drug prescriptions. When a pharmacy submits a cash transaction for a Part D Beneficiary to Requestor's claims processing vendor ("Vendor"), the Vendor processes the transaction as though Requestor were the payor. The Part D Beneficiary is then responsible for any out-of-pocket costs that are not covered by the Card. Finally, Requestor requires the pharmacist to certify that he or she has not submitted and will not submit a claim for reimbursement for the Drug to any state or federal health care program.

OIG ANALYSIS

The federal Anti-Kickback Statute makes it a criminal offense to knowingly and willfully offer or receive remuneration in an effort 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 or discounts to induce the purchase of drugs paid for by any federal health care program, including Medicare Part D.

In its analysis of the Arrangement, OIG cited its 2014 Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons.[3] In that Special Advisory Bulletin, OIG warned that copayment coupons could constitute prohibited remuneration offered to consumers to induce the purchase of specific items. When the item in question is one for which payment might be made under a federal health care program, the Anti-Kickback Statute is implicated. To read Hall Render's full overview of this Special Advisory Bulletin, click here.

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In turning to the Arrangement, OIG explained in the Advisory Opinion that the copayment coupon program utilizing the Card could improperly induce the purchase of federally payable items in two ways.

- The Card may induce Part D Beneficiaries to purchase the Drug by reducing or eliminating their out-of-pocket costs.
- The Card may induce Part D Beneficiaries to purchase other federally payable products manufactured, marketed or distributed by the Requestor.

However, OIG concluded that the Arrangement presents a minimal risk of fraud and abuse under the Anti-Kickback Statute. First, OIG stated that the Arrangement does not induce the purchase of a specific item for which payment may be made under Part D. OIG noted that a key distinction between the Arrangement and other copayment coupon programs is the fact that the Drug is statutorily excluded from coverage under Part D. Consequently, Requestor operates the Arrangement entirely outside the Medicare Part D program and also has safeguards in place to ensure that claims for the Drug are not submitted for payment under Part D. Such measures include requiring the Vendor to use claims data to detect attempted Card use by ineligible individuals, instructing pharmacies to treat Part D Beneficiaries filling Drug prescriptions as cash-paying customers and requiring Part D Beneficiaries to agree not to submit Drug claims to Part D. While these measures are not infallible, OIG viewed the fact that the Drug is excluded from Part D coverage as sufficient protection to prevent the Arrangement from inducing the purchase of a drug payable by federal health care programs.

Second, because Requestor attested that it does not and will not utilize the Arrangement as a means to market or distribute other products to federal health care program beneficiaries, OIG concluded that the risk that the Arrangement would induce Part D Beneficiaries to purchase other federally payable products manufactured or marketed by Requestor was low. Interestingly, OIG did not elaborate on this conclusion, seemingly relying on Requestor's certification as evidence that the Arrangement would not be used to induce the purchase of other Requestor items or services.

PRACTICAL TAKEAWAYS

While OIG looked favorably upon this particular discount arrangement, largely in part because the prescription drug in question was statutorily excluded from Part D coverage, OIG's concerns related to the fraud and abuse implications of prescription drug copayment coupon programs are long-standing. As discussed in the Advisory Opinion, application of certain safeguards to prescription drug discount programs may serve to reduce risk of fraud and abuse under the Anti-Kickback Statute. However, such measures are not infallible. Therefore, health care entities such as pharmaceutical manufacturers, pharmacy benefit managers, pharmacies and other health care providers that offer coupons to federal health care program beneficiaries should carefully design and closely monitor such programs so as not to run afoul of the federal Anti-Kickback Statute and other applicable fraud and abuse laws.

If you have any questions or would like additional information about this topic, please contact:

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- Your regular Hall Render attorney.

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

[1] See section 1860D-2(e)(2)(A) of the Social Security Act. [2] Individuals with commercial insurance plans may also use the Card, but the Advisory Opinion only addressed the use of the Card by Part D Beneficiaries. [3] See OIG Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (2014), available here.

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