

PUBLICATION

OIG Permits Copayment Coupon Arrangement for Statutorily Non-Covered Drug in Advisory Opinion 16-07 [Ober|Kaler]

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On June 20, 2016, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a favorable Advisory Opinion 16-07 [PDF] regarding a savings card program (Card Program) under which Medicare Part D beneficiaries receive discounts on a drug that is statutorily excluded from coverage.

The OIG reiterated its stance that copayment coupons, such as the Card Program, constitute remuneration when offered to consumers to purchase specific items for which payment may be made, in whole or in part, under a federal health care program. For reasons described below, the OIG ultimately concluded it would not impose administrative sanctions under the federal anti-kickback statute.

Under the arrangement, Medicare Part D beneficiaries use a savings card to receive discounts on out-of-pocket costs for an erectile dysfunction drug (Drug). Individuals with commercial insurance also use the Card Program for discounts towards the Drug. Although the Drug is covered by private insurance, certain federal health care programs, and some Medicaid plans, it is statutorily excluded from coverage under Medicare Part D. The requester, as marketer and distributor of the Drug, allows Medicare Part D beneficiaries to take part in the arrangement but has a process in place to try to prevent claims from being submitted for payment by Medicare Part D. Specifically, the requestor attempts to ensure that claims are not submitted for the Drug to Medicare Part D by using claims data to detect use of the Card Program by ineligible individuals, requiring Medicare Part D beneficiaries to agree not to submit claims for the Drug, and instructing pharmacies to treat such claims for Medicare Part D beneficiaries as cash-paying customers.

The OIG began its analysis by reiterating its position that copayment coupons constitute remuneration that may induce the purchase of federally payable items. The OIG cited two ways in which this can occur: (1) copayment coupons can induce the purchase of the items that are the subject of the coupon; and (2) copayment coupons can induce federal health care beneficiaries to purchase other federally payable products that are manufactured, marketed, or distributed by the manufacturer that issued the coupon. The OIG analyzed each approach in turn.

First, the OIG noted that since the Drug is statutorily excluded from Medicare Part D coverage, the copayment coupons should not induce the purchase by Medicare Part D beneficiaries of the specific item to which the coupon applies. Interestingly, the OIG suggests it may be unwilling to rely on the safeguards that the requester had put in place to avoid claims being submitted to Medicare Part D. The OIG states that such measures are “not infallible” and cites a 2014 OIG study of copayment coupons. Consequently, the OIG seems to rely most heavily on the fact that the Drug is statutorily excluded from Medicare Part D coverage.

Second, the OIG was willing to conclude that the risk that the copayment coupon could influence Part D beneficiaries to purchase other federally payable products was low based entirely on the requester's representation that it does not, and will not, use the arrangement as a vehicle to market other products. For these reasons, the OIG concluded it would not impose administrative sanctions under the federal anti-kickback statute.

While OIG advisory opinions on their face are not applicable to situations other than the requestor's specific situation, we often look to advisory opinions for clues as to how the OIG may analyze similar situations. Two aspects of Advisory Opinion 16-07 are noteworthy. First, it is instructive that the OIG went out of its way to say that efforts to prevent Part D claims from being submitted may be insufficient in that they are “not infallible.” The OIG seems to be setting a pretty high bar. Second, it is interesting that the OIG is willing to find the arrangement is “low” risk based on the representation of the requestor that it will not use the copayment coupon to market other products. The OIG would seem to be either ignoring the “good will” a company gains from coupon programs or concluding that any such good will benefit will not have a meaningful impact on purchases of other products from the manufacturer.